Consumers Health Forum of Australia

A report of findings from the rapid literature review

Medicare Benefits Schedule:

Involving the public in the review process

September 2016

About this document

This report includes a summary of findings and an appraisal of existing models used across the world to involve the public in heath technology assessment.

It is intended to inform discussions of the Medicare Benefits Schedule Review Taskforce about the 'improvement of our Medicare Benefits Schedule (MBS)' in order to ensure that it is 'consistent with the latest clinical practice, or the best value healthcare'[1]. This report focusses on ways of improving the way the public are involved in the process of reviewing MBS Items.

This report also contains an Appendix which includes the search report from the literature review, a summary of the data extracted, links to the full data set extracted from the rapid review and additional information

The report contains a level of detail intended to reflect the complex nature of the subject. As an aid, the report includes a one page summary of the entire report, and an executive summary of key learning points that have been extracted from the report.

Referencing

Documents from the literature review will be referenced throughout this report by giving the author or organisation's name, the unique reference number (created during this literature review) and a footnote URL to the original document. For example, Nunn, (A000)[2]. Other documents and citations will be cited with a footnote. Where possible URLs will direct to a publicly accessible document. Where a document is not in the public domain (for example, a journal article behind a 'paywall'), a link will be given to this document in an online shared folder created for this report.

Please note, copyrighted material is hosted for education and research purposes and appropriate arrangements should be made if disseminating in the public domain.

Archived links

Where possible, resources in the public domain reference pages on 'The Internet Archive'[3], a not-for-profit organisation which provides a free service which stores web-pages and documents as they were at certain points in time. While ensuring that references are future-proofed, the link also contains information about when the resource was accessed and 'saved', and the original full URL. For example, the date saved is highlighted here in red, the original hyperlink in purple:

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[1] http://web.archive.org/web/20151117044141/http://www.health.gov.au/internet/main/publishing.nsf/Content/922CB2933B0F1645CA257EC1001D5C12/$File/MBS%20Review_Consultation%20paper_Overview_FINAL.pdf
2 [example hyperlink]
3 https://archive.org/web/

http://web.archive.org/web/20151120043049/http://www.health.gov.au/internet/main/publishing.nsf/Content/MBSReviewTaskforce

Audience

Although this document has a specific audience, where possible it has been written in 'lay' language so that members of the public and others with no specialist knowledge may be able to understand it.

One page summary

Section title: Exploring definitions and terms

This section explores the variety of words and terms used throughout the English speaking world to describe 'consumer engagement' and associated concepts.

Key learning point

Involving the public in creating and agreeing the language used to describe engagement, participation and involvement will ensure that it is accessible, inclusive and therefore effective.

Section title: Detailed appraisal of five relevant models

This sections examines five internationally relevant models in detail, appraising the design and, where appropriate, key elements and limitations.

Key learning point

While these models represent a number of different ways of involving the public and evaluating involvement, there is no evidence-based validation for any of the models and therefore no endorsed option.

Section title: Relevant generic models of involvement

This section contains a summary of models of public involvement and engagement which, while relevant to health technology assessment, are more generic.

Key learning point

While there are a number of relevant international models, there is significant variation in the definitions of certain words used, such as engagement, and the purpose of any involvement or engagement. The Health Research Authority (UK) provides the best example of an

organisation clearly articulating what they mean by public involvement, thus providing a robust linguistic framework of reference for future involvement models[4].

Section title: Significant themes

The significant themes identified were 'social and ethical issues', 'public involvement', 'learning, training, education and development'.

Key learning point

While there may be challenges to including and involving everyone in the appraisal process, or 'tensions between equity and efficiency'[5], there are ways of overcoming some of these challenges. For example, creating inclusive learning and development opportunities for the public.

[4] http://web.archive.org/web/20151120041757/http://www.hra.nhs.uk/documents/2013/10/hra-public-involvement-strategy-circulation-september-2013.pdf (page 11)
5 http://web.archive.org/web/20151124012937/http://www.nice.org.uk/Media/Default/Get-involved/Citizens-Council/Reports/cc-report17-equity-efficiency.pdf

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Executive Summary

Introduction

This report summarises a review of international literature about ways of involving the public in heath technology assessment. It includes a summary of over fifty documents including journal articles, reports and webpages. It has also been informed by interviews with subject area experts.

In order to frame the literature, the first section 'Exploring definitions and terms' considers variations in the way definitions and terms are used to describe public involvement across the English speaking world. This section concludes with a diagram called 'Mapping the definitions' which attempts to visualise all the terms used.

In the next section, 'Detailed appraisal of five relevant models', relevant models from across the world have been summarised and appraised with key findings and limitations of each relevant model examined.

In order to provide context for the models, the 'Significant themes' section identifies important themes which emerged from the literature review. Each theme is explored in detail, identifying significant quotations and key learning points in order to help appraise and evaluate the models further. This section also contains an examination of the 'Social determinants of involvement', including diagrams which summarise the findings from the review. These diagrams may also support the MBS Review Taskforce in appraising any plans for public involvement.

Below is a summary of each section divided into a 'Summary' and 'Key learning points'

Summary of 'Exploring definitions and terms'

This section explores the variety of words and terms used throughout the English speaking world to describe 'consumer engagement' and associated concepts such as 'public involvement'.

This section begins with an examination of language used in existing MBS resources in the public domain, focussing in particular on the uses of the word 'stakeholder'.

The section then examines the differences between associated terms such as 'engagement', 'participation' and 'involvement'. It considers the question who is 'involved' or 'engaged'? The section concludes with a consideration of international literature which suggests that the term 'public' is most helpful when involving patients, consumers, carers and other people who use or may use of services in the future.

Key learning point

Involving the public in the process of creating and agreeing the language which will be used to describe engagement, participation and involvement will ensure that it is accessible, inclusive and therefore effective.

Summary of 'Detailed appraisal of five relevant models'

This sections examines five internationally relevant models in detail, appraising the design and, where appropriate, key elements and limitations. Below are short summaries of each model.

Key learning point of 'Detailed appraisal of five relevant models'

While these models present a number of different ways of involving the public and evaluating involvement there is no evidence-based validation of models for public involvement.

Summary of 'Role of patient and public participation in Health Technology Assessment and coverage decisions' (Menon, A037[6])

- Menon highlights the need for qualitative methodologies to compliment quantitative ones and identifies key stages of the HTA process, explaining the importance of public involvement at each stage
- Menon discusses the importance of public involvement not only to the public, but also to uphold the validity of the HTA process (and thus funding) itself
- Menon offers a framework for analysing public involvement in HTA. This framework 'recognizes the various facets of possible public engagement in HTA as three domains':
    - the policy making domain
    - the organizational domain
    - the research domain.

Key Issues identified by Menon

- Patients and members of the public may have different roles, and should be considered separately when they are to be involved in health technology assessment.
- There are methodological challenges with respect to how information on the 'patient experience' should be collected and synthesized.
- Since many patient organizations receive funding from industry sources there is concern about the objectivity of the information these organizations provide.
- Since not all patients share the same views it is important to canvas multiple patients and patient organizations.
- Despite a lack of evaluative evidence on the comparative merit of different approaches to engaging the public and patients there seems to be a general consensus that obtaining their perspectives is important.

[6] https://drive.google.com/open?id=0BwQTUgazNAy5UERQckEwbl96VEE

Summary of 'A Pilot Study to Identify Areas for Further Improvements in Patient and Public Involvement in Health Technology Assessments for Medicines' (Messina, A022)[7]

Key elements

The pilot study identified three key areas for 'further advancement' in the field of 'public input' in the HTA process:

Advancement 1: industry could help bring the patient perspective into the HTA process through incorporating patient experiences early in the drug development process and by including qualitative research on patient experiences in HTA dossiers. In addition 'It would be helpful to the HTA process if patients' needs and views were considered in the design of phase III research trials conducted by industry'.

Advancement 2: recognizing and supporting the role of patient advocacy groups, and making use of their access to the genuine patient perspective and experience of living with the condition in question.

Advancement 3: the continuous development of HTA systems and processes to better facilitate involvement, increase transparency and feedback, explore new options for reaching patients, and focus on creating an active and informed health consumer.

The paper includes the following 'key points for decision makers':

- The health technology assessment (HTA) of medicines should incorporate the patient's experience of what it is like living with the disease and views on the technology from the patient's perspective
- Industry can assist in acquiring patient voices by including patient views early on in drug development
- Increasing transparency and feedback, and exploring new options for reaching patients are needed

The paper also notes that 'the exact point to seek input from patients and the public is controversial'; however, it suggests that 'those involved within HTAs agree that patients/the public are usually involved too late in the process'.

[7] https://drive.google.com/open?id=0BwQTUgazNAy5WEZNN2lvejlOQkU

Summary of 'Involving patients in the early stages of health technology assessment (HTA): a study protocol' (Gagnon, A015) [8]

Key elements

- Recommends that **a third of the participants involved in the deliberation process of prioritizations topics for HTA must be patients**.
- Advocates **patient involvement in all stages of the HTA process** as patient involvement in early stages make assessments 'more relevant and acceptable' (Gagnon, A015[9]).
- Claims that methods of involvement 'that involve **face-to face interaction between participants from the public and decision makers also generate greater participant satisfaction**, both in terms of process and results' (Gagnon, A015[10]).
- Based on learning from the UK the authors suggest **patients should 'receive training** in HTA and evidence-informed healthcare before the prioritisation meetings'(Gagnon, A015[11]).
- **Patients are involved in the consultation and reviewing process** of a potential HTA topic as well as development of the assessment plan.

[8] https://drive.google.com/file/d/0BwQTUgazNAy5b3huQ2JWS1pwTm8
[9] https://drive.google.com/file/d/0BwQTUgazNAy5b3huQ2JWS1pwTm8
[10] https://drive.google.com/file/d/0BwQTUgazNAy5b3huQ2JWS1pwTm8
[11] https://drive.google.com/file/d/0BwQTUgazNAy5b3huQ2JWS1pwTm8

Summary of 'Public Participation Methods: A Framework for Evaluation' (Rowe, A051)[12]

Key elements

Rowe proposes a framework for evaluating the 'effectiveness' of the various models of participation.

The evaluation criteria are divided into:

- Acceptance criteria - related to the effective construction and implementation of a procedure
- Process criteria - related to the potential public acceptance of a procedure

Rowe provides a detailed commentary about each method and summarises the findings in the following table:

	Referenda	*Public Hearings*	*Public Opinion Survey*	*Negotiated Rule Making*	*Consensus Conference*	*Citizens' Jury/Panel*	*Citizen Advisory Committee*	*Focus Groups*
Acceptance criteria								
Representativeness of participants	High (assuming full turnout at poll)	Low	Generally high	Low	Moderate (limited by small sample)	Moderate (limited by small sample)	Moderate to low	Moderate (limited by small sample)
Independence of true participants	High	Generally low	High	Moderate	High	High	Moderate (often relation to sponsor)	High
Early involvement?	Variable	Variable	Potentially high	Variable	Potentially high	Potentially high	Variable but may be high	Potentially high
Influence on final policy	High	Moderate	Indirect and difficult to determine	High	Variable but not guaranteed	Variable but not guaranteed	Variable but not guaranteed	Liable to be indirect
Transparency of process to the public	High	Moderate	Moderate	Low	High	Moderate	Variable but often low	Low

12 http://web.archive.org/web/20151118033233/http://www.en.ipea.gov.br/participacao/images/pdfs/participacao/2000%20public%20participation%20methods.pdf

	Referenda	*Public Hearings*	*Public Opinion Survey*	*Negotiated Rule Making*	*Consensus Conference*	*Citizens' Jury/Panel*	*Citizen Advisory Committee*	*Focus Groups*
Process criteria								
Resource accessibility	Low	Low-moderate	Low	High	High	High	Variable	Low
Task definition	High	Generally high	Low	High	Generally high	Generally high	Variable but may be high	Variable but may be high
Structured decision making	Low	Low	Low	Moderate	Moderate (influence of facilitator)	Potentially high	Variable (influence of facilitator)	Low
Cost-effectiveness	Variable/low	Low	Potentially high	Potentially high	Moderate to high	Moderate to high	Variable	Potentially high

Summary of the 'National Institute for Health and Care Excellence (NICE) process' (England and Wales)

Key elements

- Appraisal committee meetings are open to the public, which promotes public understanding of how evidence is assessed.
- The Public Involvement Programme (PIP) assigns a Public Involvement Adviser to each appraisal and supports patient and carer consultee organisations, their representatives, and individual patients or carers throughout the appraisal.
- When STA are taking place, Appraisal Consultation Documents (ACD) are published on the NICE website to allow access to the public (including experts from different fields) to submit their comments. A lay version of the ACD for the public (known as 'Information for the public') is published on its website. This inclusive process allows for different perspectives to be denoted and published for the Advisory Committee to take into account.
- The public can appeal recommendations.
- The Citizens Council 'is one of the few examples of broader public engagement (as opposed to specific patients or patient advocates)' (Messina, A022)13.

13 https://drive.google.com/open?id=0BwQTUgazNAy5WEZNN2lvejlOQkU

Summary of 'Relevant generic models of involvement'

This section contains a summary of models of public involvement and engagement which, while relevant to health technology assessment, are more generic.

The section **'Understanding whose voice needs to be heard'** examines 'The ladder of participation', which can be a useful way of locating the degree of control the public have over a process, for example, the MBS Review.

It then examines a number of terms such as 'expert', 'advisor', 'advocate' and 'partner' used in other models to help articulate different roles the public can have.

The section **'National and international frameworks'** examines frameworks for 'Patient Centred Care', 'public involvement', 'citizen involvement' and 'consumer engagement'.

It includes an analysis of the International Association for Public Participation (IAP2) public participation spectrum[14], the 'Engagement Cycle'[15] and the Health Issues Centre model for consumer engagement[16].

Key learning point

While there are a number of relevant international models, there is significant variation in the definitions of certain words used, such as engagement, and the implicit purpose of any involvement or engagement. The Health Research Authority (UK) provides the best example of an organisation clearly articulating what they mean by public involvement, thus providing a robust linguistic framework of reference for future involvement models[17].

Summary of 'Significant themes'

The significant themes identified were 'social and ethical issues', 'public involvement', 'learning, training, education and development'.

The section '**Social and ethical issues'** concludes that public involvement 'increases transparency' (Wortley, A002)[18] and the 'bringing together' of the public (or representatives) with subject experts in a transparent way is key to maintaining trust in the appraisal process.

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[14] http://web.archive.org/save/https://www.iap2.org.au/resources/iap2s-public-participation-spectrum
15 https://web.archive.org/web/20150114024258/http://engagementcycle.org/engagement-strategy-culture-and-systems/
16
http://web.archive.org/web/20151126042923/http://www.healthissuescentre.org.au/images/uploads/resources/Consumer-participation-resource-for-researchers.pdf
[17] http://web.archive.org/web/20151120041757/http://www.hra.nhs.uk/documents/2013/10/hra-public-involvement-strategy-circulation-september-2013.pdf (page 11)
18 http://web.archive.org/web/20151106063004/http://www.biomedcentral.com/content/pdf/s12911-015-0176-0.pdf

A report by the NICE Citizens Council states that the transparency of such processes can affect 'perceptions that values such as justice, equality and trust are not being upheld'[19].

The section 'Public involvement' examines the failure of evidence-based medicine to involve the public and considers the social determinants of involvement.

This section concludes with two resources which have been adapted to support members of the Medicare Benefits Schedule Review Taskforce appraise their plans for involvement

The final section is a 'A checklist of questions to ask at the start of public involvement in HTA'

This short list of questions has been collated from knowledge gained from the literature review and is designed to stimulate the creation of a robust and transparent model of public involvement in the HTA process.

Why do the public need to be involved?

- Are there any exclusions, are there certain people you don't want to involve? Why?
- Are there any people who might need additional support to be involved? What support might they need?

What stage of your process are you planning to involve the public?

- Are you planning to involve them from the start? If not, why?
- Will you involve the public in helping you plan how you will involve the public?
- Do you want different people involved at different stages? Why?

How will you involve the public?

- Have you involved the public in planning how you will involve the public? For example, have you asked members of the public if they think your plans may unintentionally exclude some people?
- Have you got adequate resources or is there a limit to your involvement capacity? Have you been transparent about this limit?

How will you let people know what you are doing?

- Will the public be involved in helping you plan how you will let people know how to be involved (for example, recruitment or dissemination)?

How will you evaluate your public involvement?

- Have you planned adequate resources to evaluate involvement, including a longer term impact assessment?
- Will you publish or share the results of your evaluation so others may share in any learning?

Key learning point

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19 http://web.archive.org/web/20151120091727/http://www.nice.org.uk/Media/Default/Get-involved/Citizens-Council/Reports/cc-report17-equity-efficiency.pdf

While there may be challenges to including and involving everyone in the appraisal process, or 'tensions between equity and efficiency'[20] there are ways of overcoming some of these challenges. For example, creating inclusive learning and development opportunities for the public.

Summary of appendices

The appendices includes the following information about this literature search and report, including:

- The method - a report of what terms were searched and where
- A short discussion of inclusion and exclusion criteria
- An appraisal of the literature review, including limitations
- Output – a summary of the data extracted from the literature search

It also contains a collation of anonymised interviews conducted with staff who work to involve the public in the work of NICE.

Acknowledgements

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This is the end of the executive summary.

20 http://web.archive.org/web/20151124012937/http://www.nice.org.uk/Media/Default/Get-involved/Citizens-Council/Reports/cc-report17-equity-efficiency.pdf

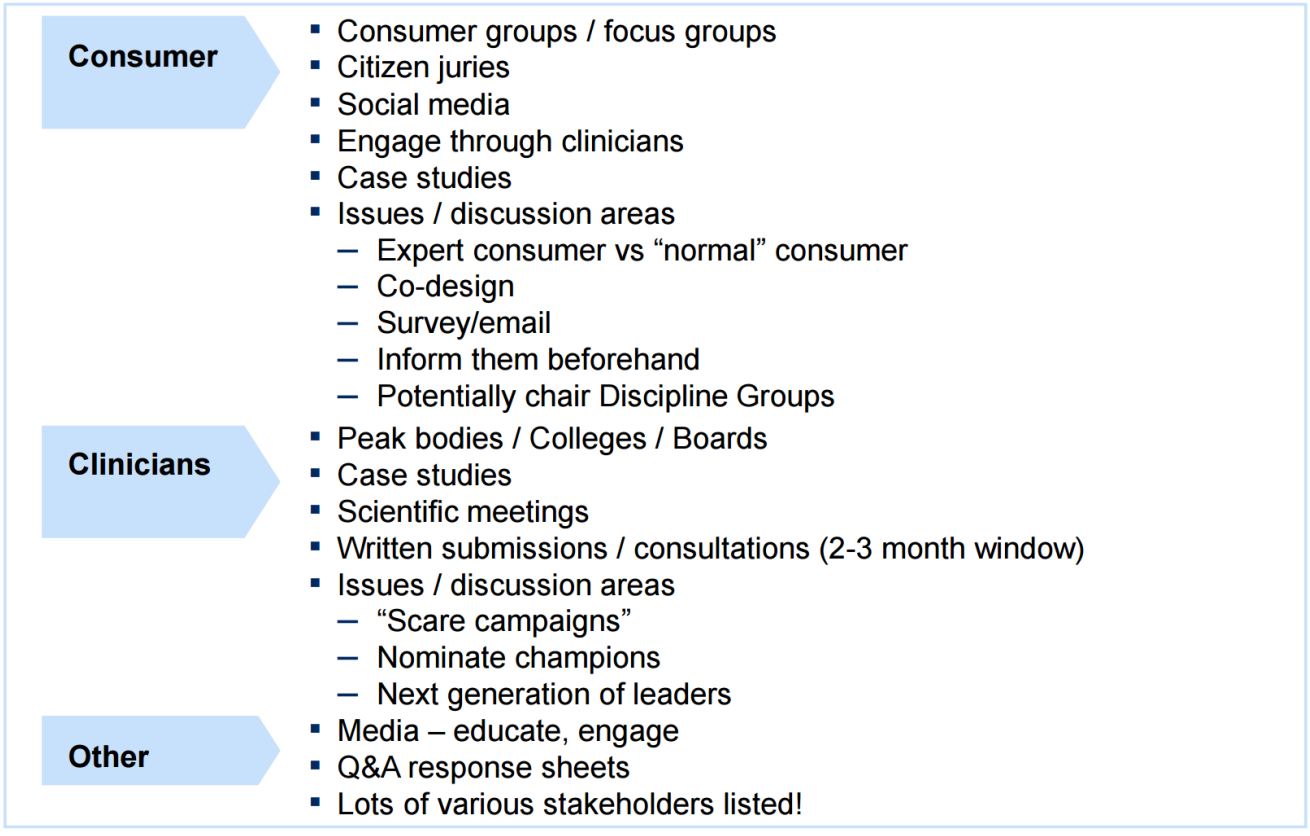
Exploring definitions and terms

Summary of language in Medicare Benefit Schedule - resources for the public

This section examines the language used in existing MBS resources in the public domain.

This slide below is taken from the 'MBS Review Stakeholder forum pack' and summarises ways of 'consulting stakeholders'. [21]

What are the most effective methods for consulting stakeholders?

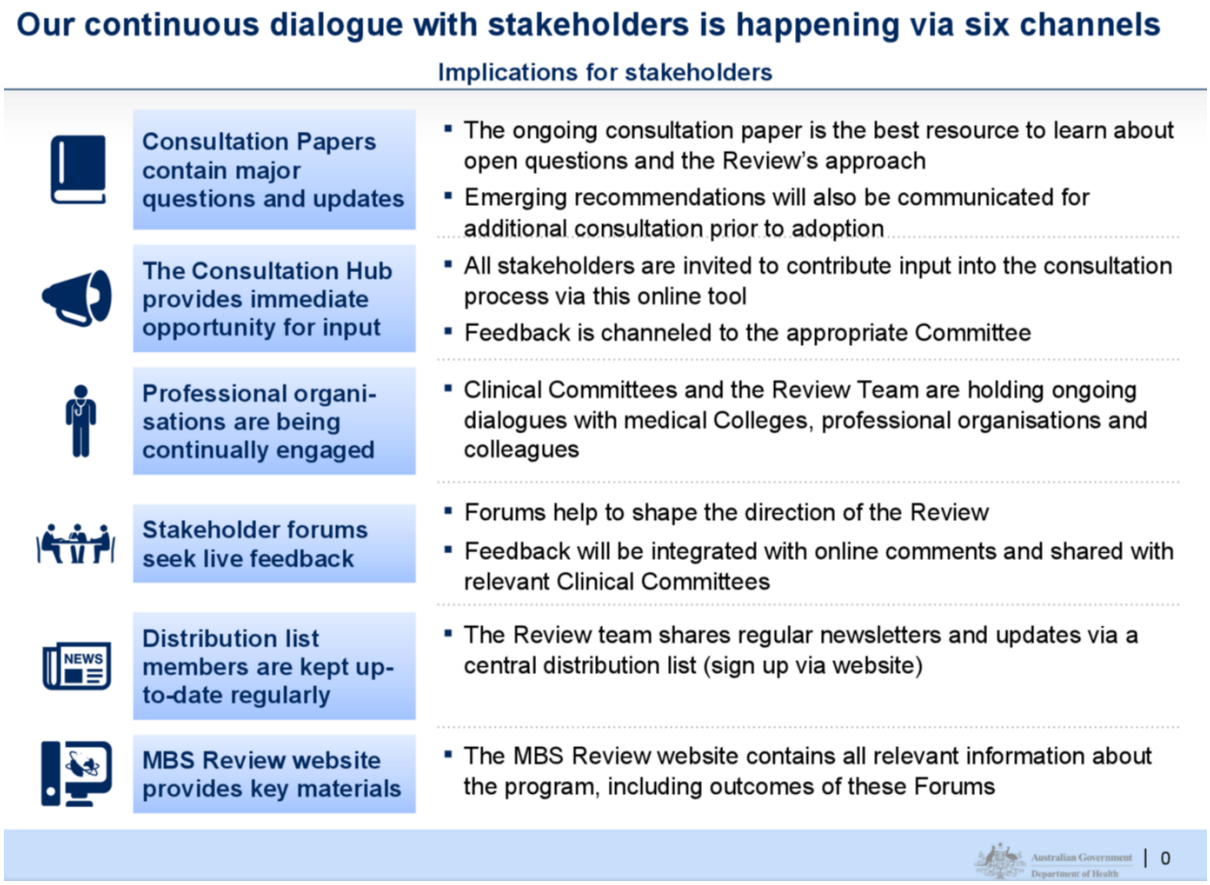


21 http://web.archive.org/web/20151117074506/http://www.health.gov.au/internet/main/publishing.nsf/Content/95453EB597B6A358CA257E590024737B/$File/MBS%20Review%20Stakeholder%20Forum%20Participant%20Pack%20-%20Perth%2025%20July%202015.pdf

In a presentation for the MBS Review Taskforce, 'stakeholders are invited to actively contribute to the refinement of rules'[22].

The same presentation asks 'What are the most effective methods for consulting stakeholders?' and 'How should consumers be engaged in the review process?', presenting two parallel sets of language around 'consulting stakeholders' and 'engaging consumers'.

The presentation also outlines how 'continuous dialogue' is taking place, with 'stakeholders' involved online (via a 'The Consultation Hub') and at 'stakeholder forums':



Summary of literature review definitions

This section summarises the different definitions of words found in the literature review. Each definition concludes with the meaning it will have in this document.

Engagement

"Generally public engagement is used as a broad term to cover a number of different types of dialogue; from basic information provision to more complex deliberation and collaboration.

22 https://drive.google.com/open?id=0B7-zEXxcoXA4YTlkR0V0X1FDYTF2b2swUnlwR0ZiZERVcjg4

Many frameworks have been published to conceptualize the differences between types of engagement with most conceptualizing a continuum whereby each successive type represents an increasing degree of influence, commitment and/or participation" (Wortley, A002)[23].

Use in this document

Engagement will be used to mean communicating with and informing people. Engaging people may lead to them knowing about and using services, or lead to them being involved in shaping them.

Health Technology Assessment (HTA)

The Australian Government defines Health Technology Assessment (HTA) as following:

"HTA is a range of processes and mechanisms that use scientific evidence to assess the quality, safety, efficacy, effectiveness and cost effectiveness of health services. HTA is commonly applied to pharmaceuticals (including vaccines), diagnostic tests, medical devices, surgically implanted prostheses, medical procedures and public health interventions. The key questions that HTA typically aims to answer for each new health technology, in comparison to alternative interventions, are:

- Is it safe?
- Does it improve health outcomes?
- Is it cost effective?

Effective assessment of health technologies includes:

- evaluating the comparative harms and benefits, using clinical evidence of patient safety, efficacy and clinical effectiveness; and
- understanding the cause, origin and prevalence of disease and knowledge of best practice treatment pathways.

A well-performing HTA system will:

- facilitate patient access to cost-effective health technologies that improve health outcomes;
- minimise the use of technologies that are ineffective or harmful;
- contribute to value for money investments in health technology in the context of limited health care resources;
- keep pace with evolving technologies, clinical practices and HTA methodologies;
- provide clear information on processes, rules and outcomes to stakeholders; and
- ensure the system is designed to achieve these outcomes in the most timely, effective, efficient and targeted way.

HTA provides an assessment and prioritising of new technologies against existing health care interventions and other government funding priorities. This process results in the best value for money for the Australian community by considering both clinical effectiveness and cost

[23] http://web.archive.org/web/20151106063004/http://www.biomedcentral.com/content/pdf/s12911-015-0176-0.pdf

effectiveness. This ensures that taxpayers' money supports health care that achieves the maximum health improvement at the lowest cost.

HTA also provides health professionals, hospitals and consumers with information about safe, high-quality and clinically effective health technologies."[24]

The European Network for HTA defines HTA as "…a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to a health technology in a systematic, transparent, unbiased, robust manner." (Menon, A037)[25]

Use in this document: HTA will refer to health technology assessement processes in general, with the MBS Review being specifically mentioned where relevant.

Medicare Benefits Schedule (MBS)

The MBS is a key component of the Medicare system. It lists all the services for which you can receive a rebate from Medicare. This includes 'out-of-hospital services provided by GPs, specialists, optometrists, and in some cases, dentists and other allied health practitioners, and where you are a private patient having in-hospital treatment (for example, if you have a baby as a private patient in a p private hospital)'.[26]

Use in this document

'MBS' will be used to describe the Medicare Benefits Schedule.

Who is 'involved' or 'engaged' - 'stakeholders', 'patients' or 'public'?

Introduction

The terms 'involvement', 'engagement' and 'participation' have different meanings across the world and are sometimes used interchangeably. Similarly, 'stakeholders', 'patient', 'public' and 'citizen' are used by many different organisations often conveying different meanings.

This section is an attempt to briefly compare and summarise a few different uses of these terms. The next section attempts to visually map them in order to help articulate the sometimes nuanced differences.

Comparison of terms

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24 http://web.archive.org/web/20151106062545/http://www.health.gov.au/internet/hta/publishing.nsf/Content/about-1

25 https://drive.google.com/open?id=0BwQTUgazNAy5UEROckEwbl96VEE

26 http://web.archive.org/web/20151117044141/http://www.health.gov.au/internet/main/publishing.nsf/Content/922CB2933B0F1645CA257EC1001D5C12/$File/MBS%20Review_Consultation%20paper_Overview_FINAL.pdf

A distinction between 'stakeholder engagement' and 'community engagement' is made in published meeting notes of a Medicare Benefits Schedule Review Taskforce Meeting, which also distinguishes between 'craft groups' and 'the wider community'[27].

In a presentation to the MBS Review Taskforce, the public was implied in the phrase 'other affected stakeholders'[28].

The following quotations indicate the plurality in the meaning of the term stakeholder:

- In HTA these stakeholders include health professionals, pharmaceutical companies, device manufacturers as well as the public and patient organizations.' (Wortley, A002)[29].
- A distinction is made between the public and patients - "ordinary or lay citizens rather than stakeholder groups such as patients or decision-makers." (Wortley, A002)[30]
- The National Institute for Health and Care Excellence (NICE) distinguishes between 'stakeholders' and 'individuals'[31]

NICE also defines a number of other related terms in an online glossary[32]. NICE uses the term 'Patient expert' and defines it as someone who has:

> 'used the technology either personally or as part of a representative group. Patient experts attend as individuals; they may be either somebody with personal experience of the condition, and if possible the technology, or a member of a patient and carer organisation for the condition being appraised'[33]

NICE also distinguishes between 'patients' and 'lay' people, with 'lay members' as part of an advisory committee:

> A lay member is a committee member with a patient, service user, carer or community background. The lay member's role is the same as other committee members, and additionally includes contributing a lay perspective and highlighting patient and carer issues.

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27 http://web.archive.org/web/20151117090839/http://www.health.gov.au/internet/main/publishing.nsf/Content/95453EB597B6A358CA257E590024737B/$File/MBSRT%20Meeting%20-%203%20July%202015%20-%20Outcomes.pdf

28 https://drive.google.com/open?id=0B7-zEXxcoXA4YTlkR0V0X1FDYTF2b2swUnIwR0ZiZERVcjg4

29 http://web.archive.org/web/20151106063004/http://www.biomedcentral.com/content/pdf/s12911-015-0176-0.pdf

30 http://web.archive.org/web/20151106063004/http://www.biomedcentral.com/content/pdf/s12911-015-0176-0.pdf

31 http://web.archive.org/web/20151120082306/https://www.nice.org.uk/article/pmg19/chapter/glossary

32 http://web.archive.org/web/20151120082306/https://www.nice.org.uk/article/pmg19/chapter/glossary

33 http://web.archive.org/web/20151120082306/https://www.nice.org.uk/article/pmg19/chapter/glossary

NICE also distinguishes between 'patients, carers and the public', stating they are 'committed to involving patients, carers and the public in the development of its guidance and other products'[34].

NICE defines a 'carer' as 'a person who provides unpaid care by looking after a relative, friend or partner who needs support because of ill health, frailty or disability'.

The Canadian Agency for Drugs and Technologies in Health (CADTH) distinguishes between 'patients', 'stakeholders' and 'anyone with an interest' in their work[35]:

> 'Listening to patients is a vital part of CADTH's work. We recognize that patients have unique knowledge about what it is like to live with a specific disease or medical condition. They can describe advantages and disadvantages of current therapies, which may not be reported in published literature. And they can tell us what they would most value from a new treatment. We also know that there may be other stakeholders — individuals and organizations — with important insights to contribute to our work… Eligibility to provide feedback varies depending on the CADTH product, but it is often open to anyone with an interest in the work.'

The Scottish Medicines Consortium (SMC) has a webpage titled 'public involvement', but doesn't use the term public on the page, with the heading 'Capturing the patient and carer voice[36]':

> Understanding the experiences of patients, their families and carers is a key element in our decision making process. It is important for SMC members to fully understand how a new medicines impacts the quality of life of patients and carers. This enables them to make a fully informed decision on whether or not to recommend a new medicine. Patients, members of their families and carers can provide unique knowledge about what it's like to live with a condition. They can explain advantages and disadvantages of medicines that may not be available in the published literature or quality of life measures. We work in partnership with patient groups to gather this information through our patient group submissions.

On a separate page the SMC uses the term 'public', stating 'the Public Involvement Network (PIN) Advisory Group helps SMC to continuously improve how we involve patients, carers and members of the public in our work'[37].

'Participation' is often used to mean 'involvement' yet there is potential for confusion as 'research participants' or people 'participating in research' has a very specific meaning.

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34 http://web.archive.org/web/20151120090945/https://www.nice.org.uk/about/nice-communities/public-involvement

35 http://web.archive.org/web/20151124003854/https://www.cadth.ca/provide-input

36 http://web.archive.org/web/20151124004918/https://www.scottishmedicines.org.uk/Public_Involvement/Public_Involvement

37 http://web.archive.org/web/20151124005229/https://www.scottishmedicines.org.uk/Public_Involvement/Public_Involvement_Network_Advisory_Group

Similarly, organisations often say 'engagement' when they mean involvement and vice versa. Accordingly, INVOLVE (UK) provides this helpful articulation of the terms:

> 'Researchers and others use different words to describe public involvement, for example words such as engagement and participation. When INVOLVE uses the term 'public involvement' we are not referring to researchers raising awareness of research, sharing knowledge or engaging and creating a dialogue with the public. We are also not referring to the recruitment of patients or members of the public as participants in research. However, these different activities – involvement, engagement and participation – are often linked and, although they are distinct, can complement each other. For example, the public can and do play a valuable role in advising on recruitment of patients as participants and on ways of engaging with the public'[38].

Who are 'the public'?

In the paper 'Role of patient and public participation in health technology assessment and coverage decisions', Menon writes:

> 'Published work on public involvement in healthcare has defined a number of 'publics'. They include patients and users of health services, caregivers, taxpayers and representatives of these publics, such as elected officials and patient advocacy groups. Such groups are not always mutually exclusive, with individuals belonging to more than one at any given time. This article considers two specific groups: citizens, representing society (**who will be referred to as the 'public'**) and patients, as users of the health system. Although patients are also members of the public, for the purpose of this paper, their 'engagement' in HTA will focus on their experience living with a condition requiring interactions with the health system' (Menon, A037)[39]

Menon goes on to state:

> '**Patients offer important insights into the value of a technology through first-hand experience** with the condition in which the technology is used. By contrast, **the public, representing taxpayers, may provide input into the 'relative value'** of a technology when compared with other services under consideration for funding at the same time' (Menon, A037)[40]

The use of the term 'public' reflects a shift in language (and perhaps attitudes) both domestically and internationally.

The Health Research Authority in England provides a helpful definition of the word public, stating;

> 'When we use this term, public means patients, potential patients or members of the public including those with known genetic dispositions, carers and people who use

38 http://web.archive.org/web/20151126053458/http://www.invo.org.uk/find-out-more/what-is-public-involvement-in-research-2/
39 https://drive.google.com/file/d/0BwQTUgazNAy5UERQckEwbl96VEE/
40 https://drive.google.com/file/d/0BwQTUgazNAy5UERQckEwbl96VEE/

> health and social care services as well as people from organisations that represent people who use health and social care services'[41]

Similarly, INVOLVE (a UK organisation which is funded by the National Institute for Health Research, to support active public involvement in NHS, public health and social care research) states:

> 'When using the term 'public' we include patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services. Whilst all of us are actual, former or indeed potential users of health and social care services, there is an important distinction to be made between the perspectives of the public and the perspectives of people who have a professional role in health and social care services'[42].

The previous two definitions are analogous to one used by the National Health and Medical Research Council (NHMRC) in the 'Draft Statement on Consumer Involvement in Health and Medical Research', which defined the word consumer as:

> 'patients and potential patients, research participants, carers, consumer organisations and members of the public'[43]

Similarly, the 'Public Involvement Programme' (PIP) is a team at the National Institute for Health and Care Excellence (NICE) that 'develops and supports patient, carer and public involvement'.[44]

Use in this document

The term 'public' has been used in this document, reflecting the language used in the recommendations section of the Senate Community Affairs References Committee report *'The availability of new, innovative and specialist cancer drugs in Australia'*, where it states a need to improve ways of 'incorporating public perspectives on overarching moral, ethical and opportunity cost considerations into PBAC decision making processes'[45].

'Public involvement' will be used throughout, to be understood to also include 'consumer, patient and carer involvement'.

Please see the next section 'Mapping the terms' for a visual explanation of these concepts.

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41 http://www.hra.nhs.uk/documents/2013/10/hra-public-involvement-strategy-circulation-september-2013.pdf

42 http://web.archive.org/web/20151126053458/http://www.invo.org.uk/find-out-more/what-is-public-involvement-in-research-2/

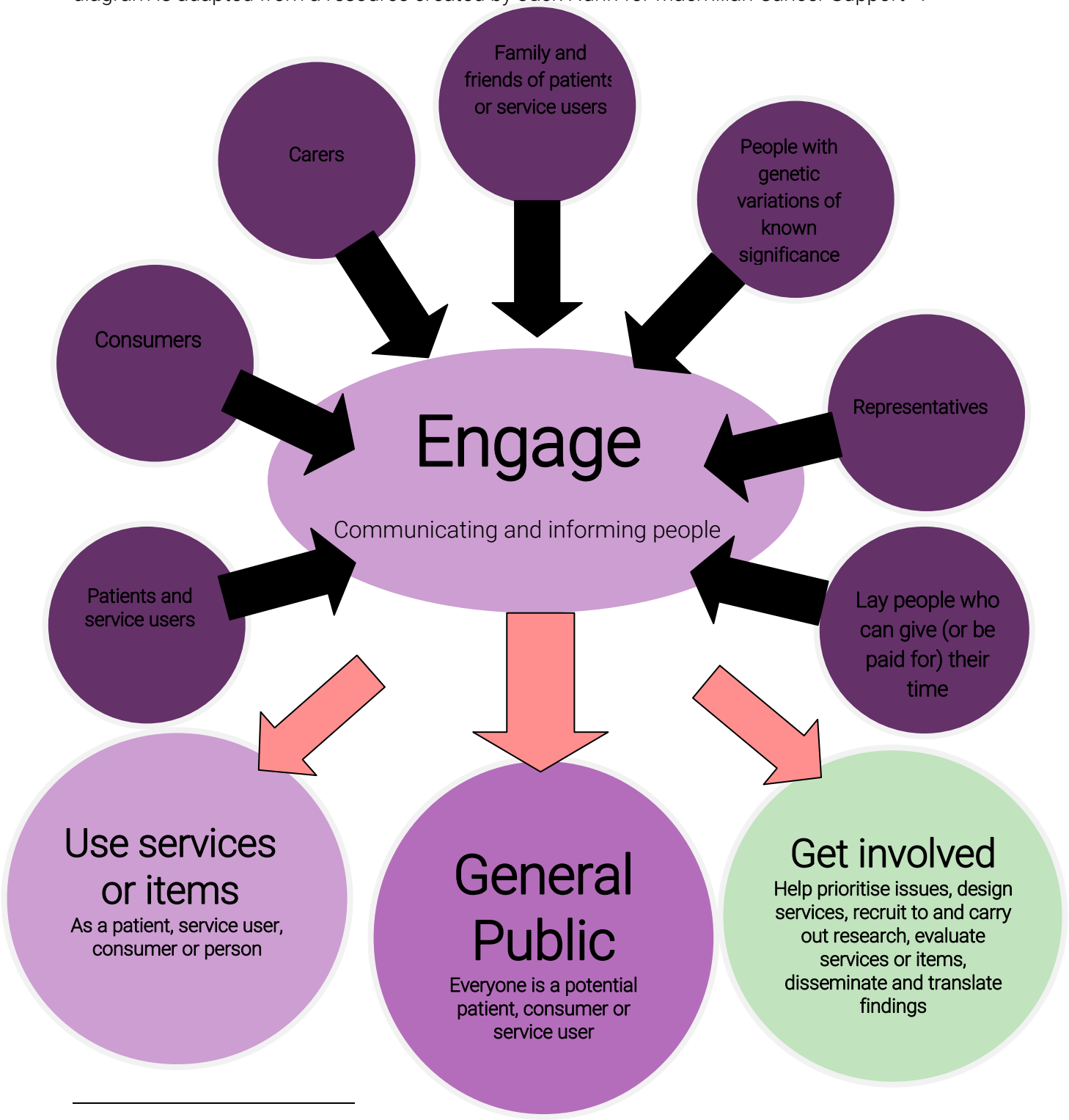
43 http://consultations.nhmrc.gov.au/files/consultations/drafts/draftconsstatementconsultationversion140807.pdf

44 https://www.nice.org.uk/about/nice-communities/public-involvement/public-involvement-programme

45 http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Cancer_Drugs/~/media/Committees/clac_ctte/Cancer_Drugs/Report/report.pdf

Mapping the definitions: Diagram of engagement, participation and involvement in research

This diagram attempts to map the various definitions and terms explored in this report, to aid a discussion about the most helpful terms to use at which stages of the MBS Review. This diagram is adapted from a resource created by Jack Nunn for Macmillan Cancer Support[46].



[46] http://web.archive.org/web/20151120021821/http://learnzone.org.uk/courses/course.php?id=109

Detailed appraisal of five relevant models

This sections examines five internationally relevant models in detail, summarising the design and where appropriate identifying key elements and limitations. Rather than being a selection of 'key models' these five models represent the only directly relevant models found during the literature search.

After the detailed appraisal of these models is a short section summarising two other significant models which contain useful elements.

Appraisal of 'Role of patient and public participation in Health Technology Assessment and coverage decisions' (Menon, A037[47])

This diagram displays the main phases within the Health Technology Assessment process. This process begins with 'Innovation' at the initial phase and 'Abandonment' or 'Obsolescence' at its conclusion.

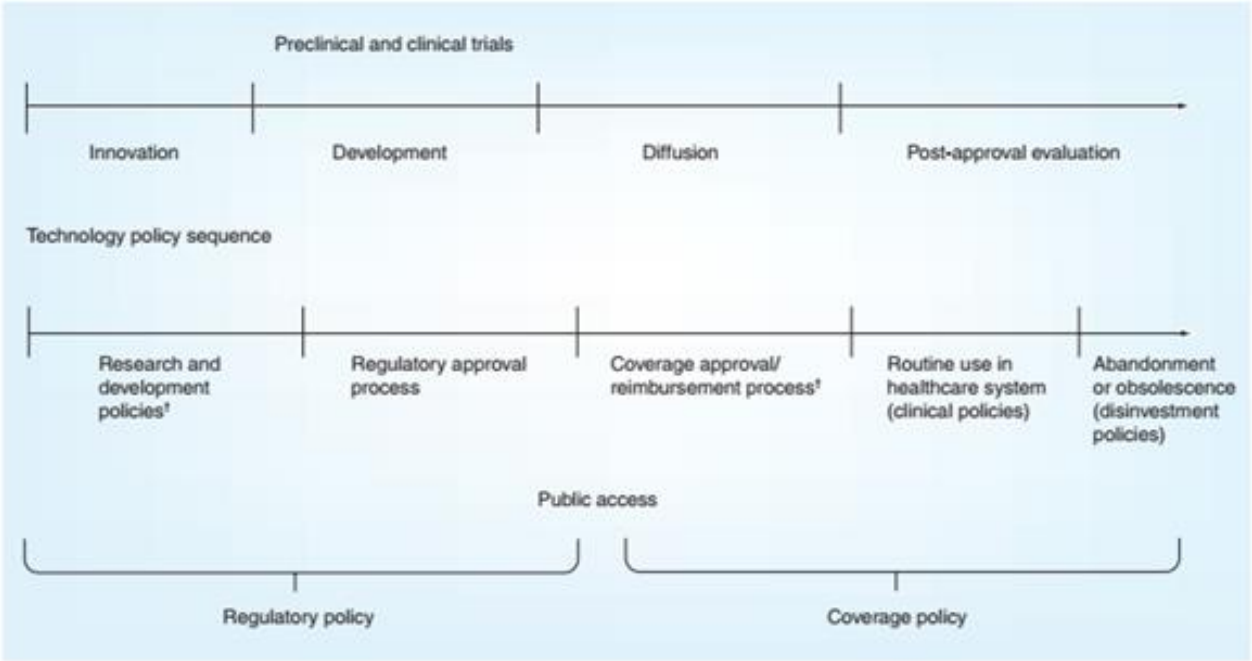


Figure 1. Relationship between the life cycle of a technology and a technology policy.
†Points at which the public has been involved in health technology policy.

This model raises the question about where in this process the public are currently involved, and where involvement could be developed or improved.

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[47] https://drive.google.com/open?id=0BwQTUgazNAy5UERQckEwbl96VEE
This document was created by Jack Nunn for the Consumer Health Forum on 11 October 2016. To give feedback, send an email or contact @JackNunn.

Summary of differences between leading countries

Based upon the research of Menon and Stafinski, the following have been identified as current mechanisms employed by various countries, states or provinces:

Phase	Process
Identification of technologies	• 64% of national processes and 75% of state processes involved the public in identifying technologies for assessment/potential coverage. • In general the referral process involved completion of a downloadable 'application form' located on the respective organizations website.
Selection of technologies for assessment (priority setting)	• With two exceptions (NICE, UK and Centers for Medicare and Medicaid Services, CMS) none of the national, state or provincial processes sought input from patients or the public in the selection of technologies for assessment
Conduct of HTA (including defining the scope of the HTA)	• All but one national process elicited the views of patients and/or the public during the actual assessment. • Two processes included patient representatives on committees tasked with defining the scope of assessment (Australia and France). • One sought input into the scope from patient/carer organizations (UK) and another from anyone (Germany). • Several processes invited anyone (Germany) or patient representatives (France & UK) to comment on draft protocols. • Patients/carers were able to submit information to the body responsible for preparing the assessment directly (Germany), through patient/ carer organization 'group' submission (Canada, France, UK) or through the appointment of a patient representative to the advisory group overseeing the assessment (Australia). • Two of the processes accepted information from anyone (Germany and USA). • One process facilitated input from patients through dedicated patient and public involvement subcommittee, which also included three members of the general public (Scotland). • In one process, submissions were accepted only if requested by the decision making committee (New Zealand).

	•
Review of the HTA results and formulation of recommendations	• Committee membership-appointment of at least one patient representative to the committee responsible for making funding recommendations (Australia, France, Germany [in the German committee the patient is a non-voting member]). • Presentation of written or oral testaments from patients (consumer impact statements) – either by committee invitation (Australia, The Netherlands) or at the request of the patients/carer organization (UK). • Opportunities to review HTA report and draft recommendations- (France and UK). Patient representatives included on committees were typically recruited through patient/carer organizations. In one process, the role of the public in this step was limited to committee membership (Canada) or commenting upon draft recommendations (Germany and the USA. Finally, several processes held committee meetings partly in public (UK).
Implementation of recommendations/decisions	• Generally, public or patient involvement in the implementation of recommendations was limited to the launch of appeals against recommendations. With two exceptions (UK and USA), only those who represented the 'applicant' could initiate the appeal (Australia).
Dissemination of decision and HTA findings	• The majority of national and provincial/ state level processes posted reports and decisions/ recommendations on organizational websites. However, neither stakeholder group appeared to be actively involved in the dissemination of such information.

Australia: Detailed analysis

Advisor and/or decision maker	Identification of technologies		Selection of technologies for assessment		Undertaking of HTA		Review of HTA results and formulation of recommendations		Implementation of recommendations/ decisions		Dissemination of decision/HTA findings		Ref.
	Patients	*Public*	*Patients*	*Public*	*Patients*	*Public*	*Patients*	*Public*	*Patients*	*Public*	*Patients*	*Public*	
National level													
Australia	Yes	Yes	No	No	Yes	No	Yes	No	Yes	No	Yes	No	[16,102, 109–114]
• Department of Health and Ageing (decisions) • Pharmaceutical Benefits Advisory Committee (recommendations)	Technologies may be referred by anyone		NA		Patients and/or carers may provide advice during preparation of HTA through committee membership		If the 'applicant' is a patient or carer organization, it may provide advice and/or comment on the evaluation report If the 'applicant' is a patient or carer organization, it may present views during committee/board meeting Committee includes a 'consumer' (patient representative) Written patient statements describing condition ('consumer impact statements') may be requested by and provided to the committee		If the 'applicant' is a patient or carer organization it may appeal the decision		If the 'applicant' is a patient or carer organization it may provide comments on a summary document containing final decisions before it is published on the organization's website The 'applicant' may appeal the decision		
Australia	Yes	No	No	No	Yes	No	Yes	No	NA	NA	NA	NA	[115–122]
• Department of Health and Ageing (decisions) • Medical Services Advisory Committee (recommendations)	Technologies may be referred by patients and/or carer organizations		NA		Patients and/or carers may participate in defining the scope of the HTA If the 'applicant' is a patient or carer organization, it may nominate a clinical expert to offer advice May nominate an individual (through Consumer Health Forum of Australia) to serve on advisory panel		If the 'applicant' is a patient or carer organization, it may nominate clinical experts to be contacted for advice during assessment If the 'applicant' is a patient or carer organization, it may provide comments on the report and draft recommendations Committee includes a 'consumer' (patient representative)		No information found		No information found		

England (NICE) – Detailed analysis

England, Wales and Northern Ireland	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	NA	NA	[16,30,31, 110,122, 134, 153–157]
• NICE (decisions) • NICE Technology Appraisals Committee	Technologies may be referred by anyone		Topic selection panel includes patient and/or carer representatives		Patient or carer organizations may participate in defining the scope of the HTA Patient and/or carer organizations may submit information to group preparing HTA		Patient and/or carer organizations may nominate clinical or patient experts to present oral testaments to committee Patient and/or carer organizations may provide comments on report and draft recommendations Parts of committee meetings held in public		Patients and/or carer organizations may appeal recommendations		No information found		

Key elements

"Health technology policy making cannot be reduced to a technical exercise, free from values or ethical judgements."

Menon highlights the need for qualitative methodologies, to compliment quantitative ones:

> 'Well-accepted methods to collect clinical trial data, scales to assess the quality of clinical trials and guidelines for the conduct of economic evaluations already exist and are adhered to by most HTA producers. However, patients' experiential information will, at least to some extent, be qualitative, requiring different methodological approaches (e.g., focus groups and interviews). Although the published literature encourages the collection and use of such information, it offers little guidance on rigorous approaches to accomplish this, given the time and resource constraints faced by most HTA bodies.'

Menon identifies keys stages of the HTA process, explaining the importance of public involvement at each stage:

> Completing a HTA involves several steps, including: identifying the 'right' questions; defining the appropriate outcomes and other measures; collecting, analyzing and synthesizing information; and writing a report intended for decision-maker.

Menon continues:

> 'Patients should be involved in all of these steps to ensure that HTA adopts a health condition perspective, rather than a technology perspective. It is argued that their input will identify questions to be addressed that differ from those typically formulated by HTA agencies, governments or payers. Patients' views on what constitutes 'value' may not be the same as those of clinicians or trialists. This may lead to the identification and selection of outcome measures that do not capture critical aspects of 'benefit' to patients (e.g. preferences regarding the management of their condition). Through active involvement of patients in this step, such concerns could be alleviated'

Menon cites the European Network for HTA, which defines HTA as 'a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to a health technology in a systematic, transparent, unbiased, robust manner'.

Menon writes about the role of the 'public' and 'patients'. Please note that this content is repeated and highlighted in the section 'Exploring definitions and terms'.

- 'Published work on public involvement in healthcare has defined a number of "publics". They include patients and users of health services, caregivers, taxpayers and representatives of these publics, such as elected officials and patient advocacy groups. Such groups are not always mutually exclusive, with individuals belonging to more than one at any given time. This article considers two specific groups: citizens, representing society (who will be referred to as the 'public') and patients, as users of the health system. Although patients are also members of the public, for the purpose of this paper, their 'engagement' in HTA will focus on their experience living with a condition requiring interactions with the health system'.

- 'Patients offer important insights into the value of a technology through first-hand experience with the condition in which the technology is used. By contrast, the public, representing taxpayers, may provide input into the 'relative value' of a technology when compared with other services under consideration for funding at the same time'.

Menon discusses the importance of public involvement not only to the public, but also to uphold the validity of the HTA process (and thus funding) itself:

> 'Unless greater effort is made to involve patients and citizens in determining priorities, in evaluating the efficacy and cost–effectiveness of healthcare interventions, and even more importantly, in using the results of these evaluations to make informed choices, HTA will have little chance of achieving its goals. It will also be hard to sustain public support for funding HTAs if the public remains ignorant of its importance and relevance to them. It is assumed that through active patient involvement in identifying and selecting technologies, those that are 'really important' (i.e., those that matter to people suffering an illness and therefore impact health) will be chosen for assessment. This could, in turn, change the perception of HTA from a 'gatekeeper' to an 'enabler' of effective new technologies. At present, criteria for identifying and selecting technologies for assessment are typically developed or adopted and used by HTA agencies without the direct involvement of patients or the public.'

Menon summarises the HTA process in the following way:

- Identification of technologies
- Selection of technologies for assessment (priority setting)
- Conduct of HTA (including defining the scope of the HTA)
- Review of HTA results and formulation of recommendations (e.g., fund, fund with conditions, provide interim funding and disinvest)
- Implementation of recommendations/decisions
- Dissemination of decision and HTA findings

Evaluation framework

Menon offers a framework for analysing public involvement in HTA. This framework 'recognizes the various facets of possible public engagement in HTA as three domains':

- the policy making domain
- the organizational domain
- the research domain.

Each domain 'comprises a series of activities, including priority setting for assessments, collection of evidence and synthesizing data. A dedicated literature search for information describing its validation or application was conducted, but no studies were found.'

Key Issues identified by Menon

- Patients and members of the public may have different roles and should be considered separately when they are to be involved in health technology assessment.
- There are methodological challenges with respect to how information on the 'patient experience' should be collected and synthesized.
- Since many patient organizations receive funding from industry sources, there is concern about the objectivity of the information these organizations provide.

- Since not all patients share the same views it is important to canvas multiple patients and patient organizations.
- Despite a lack of evaluative evidence on the comparative merit of different approaches to engaging the public and patients, there seems to be a general consensus that obtaining their perspectives is important.

Limitations

The 'decentralized nature' of health-care systems and the international variation makes meaningful detailed comparisons challenging.

Although a 'one-size-fits-all approach to HTA may be appropriate for certain technologies', location specific information and data is playing an increasingly important role in decision making, for example, 'patient preference, resource implications, ethical considerations, implementation issues'.

This increasingly localised system limits the way in which meaningful comparisons can be made between systems, although it is not a barrier to learning from the different kinds of involvement.

Appraisal of 'A Pilot Study to Identify Areas for Further Improvements in Patient and Public Involvement in Health Technology Assessments for Medicines' (Messina, A022)[48]

The objective of this paper was to 'conduct a pilot study to form the basis of future research and to gain insight into how to practically and meaningfully advance patient and public input in HTAs for medicines' (Messina, A022)[49].

The authors 'apply learning from health systems in Australia, Canada, and the UK to focus on the practical aspects of engagement'. Australia's 'patient and public participation within the HTA process is not as systematic as the English model; however, public involvement in the decision making process can take on three distinct forms: committee member representation, brief patient group submissions via a template process and, most recently, more detailed consumer impact statements'.

Consumer impact statements 'are a PBAC pilot program in Australia that utilize qualitative research to examine what it is like to live with a particular disease or condition, for which a new treatment will be considered'. The authors state that:

> 'While these documents have been cited as useful in the medicine HTA process, to date they are only used for rare or poorly understood conditions where the committee will require more evidence on the patient's quality of life and experience living with the condition'(Messina, A022)[50].

The pilot study identified three key areas for 'further advancement' in the field of 'public input' in the HTA process:

Advancement 1: Industry

- Industry could help bring patient perspectives into the HTA process through incorporating patient experiences early in the drug development and by including qualitative research on patient experiences in HTA dossiers.
- This will place a greater importance on the patient as an 'adviser'.
- The patient's perspective can provide rich and valuable data when incorporated early on in the technology development stage, allowing patients to voice their opinions and exert some influences early on in the process. However, the legal and regulatory constraints that may exist need to be considered and navigated.

[48] https://drive.google.com/open?id=0BwQTUgazNAy5WEZNN2lvejlOQkU
[49] https://drive.google.com/open?id=0BwQTUgazNAy5WEZNN2lvejlOQkU
[50] https://drive.google.com/open?id=0BwQTUgazNAy5WEZNN2lvejlOQkU

- There is an imperative need to integrate qualitative methods in the HTA process so that rich accounts of the patient experience are captured. Scientific quantitative methods alone fall short of capturing integral patient information, perceptions and attitudes.
- Industry need to give careful consideration to what it is like living with a particular disease and how any new technology might improve patient experience.

Advancement 2: Patient Advocacy Groups

- Recognizing and supporting the role of patient advocacy groups and making use of their access to the genuine patient perspective and experience of living with the condition in question.
- Patient groups should be properly supported along the way so that they can make a meaningful contribution to the process.
- Patient groups should be given early notice of upcoming product reviews to ensure they have adequate time to organize a patient submission. For example, in Australia, patient advocacy groups have a 2-week window to make submissions to the PBAC. Industry need to ensure that timelines do not pose a barrier to patient engagement.
- Patients feel intimidated by the process and need to be adequately supported so that they don't feel like outsiders to the HTA process.
- The paper also outlines a number of recommendations for learning and development which can be found in the section 'Creating opportunities for learning, education, training and development'.

Advancement 3: HTA Process Developments

- The continuous development of HTA systems and processes to better facilitate involvement, increasing transparency and feedback, exploring new options for reaching patients and focusing on creating an active and informed consumer.
- Adequate mechanisms for feedback in the process were noted as suitable options for enhancing consultations in HTA's.
- Goals, priorities, and outcomes for the health system should be discussed in open forums with wider health stakeholders.
- Education and training to patients and the public so they can be active and informed consumers who are health literate and can contribute to the development and progression of medicine HTA's. An educated public can provide quality information on citizen's values, needs, judgments, prioritization and technology preferences.
- A proper feedback mechanism needs to be developed in order to address how patient input was utilized in the HTA process.

Framework for increasing patient and public engagement in medicine health technology assessments

The following framework outlines 'ways of increasing patient and public engagement in medicine health technology assessments'. It was formulated based on the pilot study conducted by Messina and Grainger, which utilized semi- structured interviews with agencies, experts and patient and advocacy groups in Australia, Canada and the UK.

Table I. Framework for increasing patient and public engagement in medicine health technology assessments

HTA advancement areas
1. Industry
Qualitative research by the sponsor
Industry focus on QOL
Earlier consideration of the impact of 'living with the disease'
Inclusion of the patient's perspective in sponsor dossiers
2. Patient advocacy groups
Third-party facilitated discussion with patient advocates
Adding context to HTA data including QOL and clinical outcome measures
Timely notification of new products
Time to commission research and ensure support for patient engagement
Delivery of patient submissions and nomination of advocates to represent patients
3. HTA process development
Wider discussion of the role of HTA in the health system
Educate patient advocacy groups and HTA committees on the HTA process
Consideration of new media options
Development of new methods to reach patients/the public
Increased process transparency
Document meeting outcomes including the value of patient input
Formal audit of the process
Understanding values and priorities
Citizens' juries
Health literacy
Promotion of active and informed consumers

HTA = health technology assessment; **QOL** = quality of life.

Significant quotations from interviewees

These direct quotations from respondents 'serve to illustrate larger themes from the interview data collected in this study'.

"*You should have meaningful involvement of patients throughout the process, on an equal footing to other members of an assessment group, and that your money should be invested in good qualitative research to determine* [*the*] *patient's perspective … that has to happen very early, because qualitative research takes time … and so it needs to be identified early in the process and, indeed, from a pharmaceutical company perspective, I think qualitative research should be happening earlier in drug development.*" (Agency/expert, the UK)

"*To start off, I think there needs to be more of an education about HTA and the process. It needs to be explained in such a way that people who don't have any prior experience can understand it.*" (Patient advocacy, the UK)

"*I think it's the time pressures – by the time people* [patients] *get around to thinking 'I want to put something in* [a patient submission]*' it's almost too late … it's gone … so it isn't enough time.*" (Agency/expert, Australia)

"*Patients often bring a very unique perspective … and cut through to the real issues: 'okay, this means if I get this drug, this means I can afford to pay my mortgage and receive treatment that will keep me alive for another couple of years.'*" (Patient advocacy, Australia)

"*Patients are the ultimate end user of any technology and they can tell us more about living with the disease, actually using the technology, and any challenges they find, than anybody else can.*" (Agency/expert, the UK)

"*I would like some sort of* [*new improvement*]*, that patients or citizens would be equal partners with other groups that input on decision making, so their voice would be seen as an equal partner … with those other pieces of evidence.*" (Academic/expert, Australia)

Identified mechanisms to improve public involvement in the HTA process

The paper outlines the following areas for improvement and recommends mechanism for improving them. These areas and mechanisms are summarised in the table below.

Area for improvement	Mechanism
Lack of education which leads to poorly produced patient submissions.	Patient and advocacy groups to be supported by industry with education and training as to how to produce a good submission.
Inadequate feedback and transparency channels	A formal audit would provide a clear understanding of how patient input was utilised in HTA decision making.
Lack of public or consumer involvement	Considering new media options is likely to increase patient and public engagement as more people are turning to media for health information. It may also be possible to gain access to patient and public views through blogs and other social media platforms.
Limited involvement in health policy decision making	Open forums where patients and the public would be welcome to be part of wider health policy decision making.

Key elements

The pilot study identified three key areas for 'further advancement' in the field of 'public input' in the HTA process:

Advancement 1: industry could help bring the patient perspective into the HTA process through incorporating patient experiences early in the drug development process and by including qualitative research on patient experiences in HTA dossiers. In addition 'It would be helpful to the HTA process if patients' needs and views were considered in the design of phase III research trials conducted by industry'.

Advancement 2: recognizing and supporting the role of patient advocacy groups, and making use of their access to the genuine patient perspective and experience of living with the condition in question.

Advancement 3: the continuous development of HTA systems and processes to better facilitate involvement, increasing transparency and feedback, exploring new options for reaching patients, and focusing on creating an active and informed health consumer.

The paper includes the following 'key points for decision makers':

- The health technology assessment (HTA) of medicines should incorporate the patient's experience of what it is like living with the disease and views on the technology from the patient's perspective
- Industry can assist in acquiring patient voices by including patient views early on in drug development

- Increasing transparency and feedback, and exploring new options for reaching patients are needed

The paper also notes that 'the exact point to seek input from patients and the public is controversial; however, it suggests that 'those involved within HTAs agree that patients/the public are usually involved too late in the process'.

Limitations

The exploratory nature of this pilot study uncovered 'various themes and advancements to the current HTA systems in Australia, Canada, and the UK'. The authors note that 'these findings may be subject to change if the same questions were asked to a larger sample':

> 'While we would expect similar themes to emerge in a larger sample, there may be additional explanations and discussions of areas for improvement that materialize in a larger sample. Another limitation of this research is the selection of the three geographic case studies in which we sampled. Since experiences and knowledge are linked to each respondent's HTA system and country, the findings presented in this paper are most relevant to Australia, Canada, and the UK'

The paper only examines models in the English speaking world, although 'the suggested areas of advancement certainly have applications to HTA systems across the globe'.

Appraisal of 'Involving patient in the early stages of health technology assessment (HTA): a study protocol' (Gagnon, A015) [51]

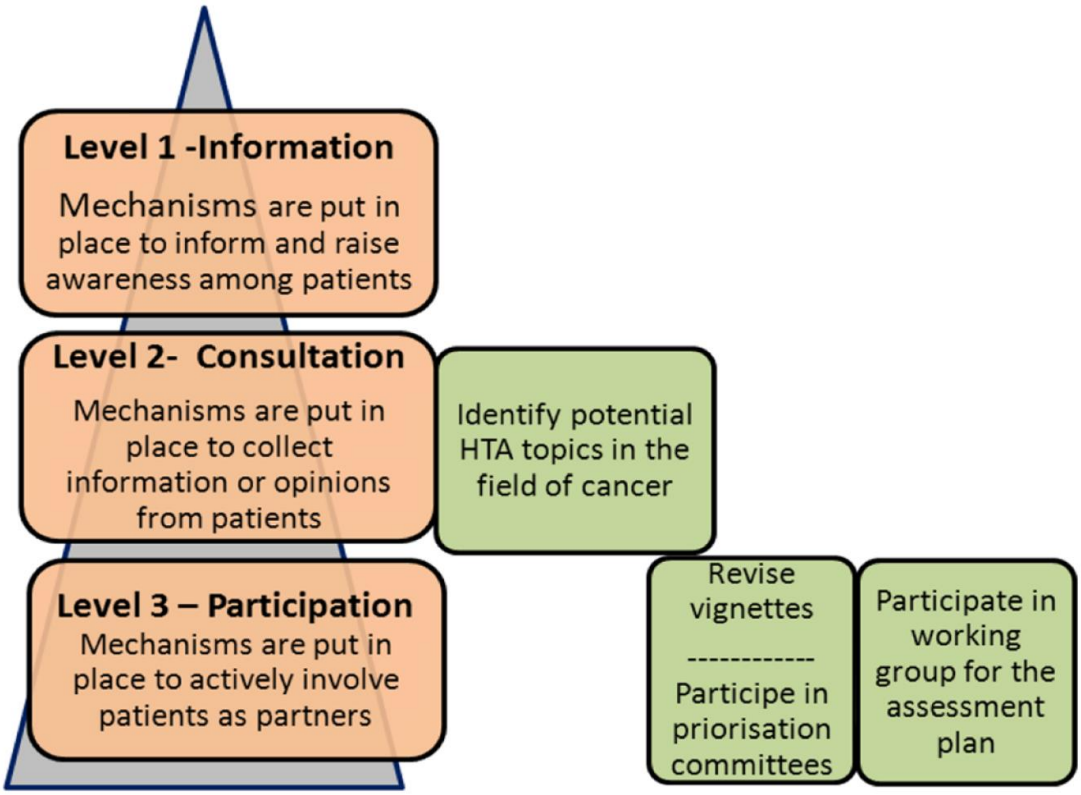
Model for HTA

This model depicts interventions to promote patient involvement in the early stages of the HTA process, as 'in health technology assessment (HTA), public and patient involvement is also considered as a priority' (Gagnon, A015[52]). The three levels of patient involvement are:

1. Communication and information – Mechanisms are put in place to inform and raise awareness among patients.
2. Consultation- Mechanism are put in place to collect information or opinions from patients.
3. Active participation- Mechanisms are put in place to actively involve patients as partners, which is considered the most advanced form of involvement.

Here is an extract from the model (please note the authors intended the word 'participate', not participle):

[51] https://drive.google.com/file/d/0BwQTUgazNAy5b3huQ2JWS1pwTm8
[52] https://drive.google.com/file/d/0BwQTUgazNAy5b3huQ2JWS1pwTm8

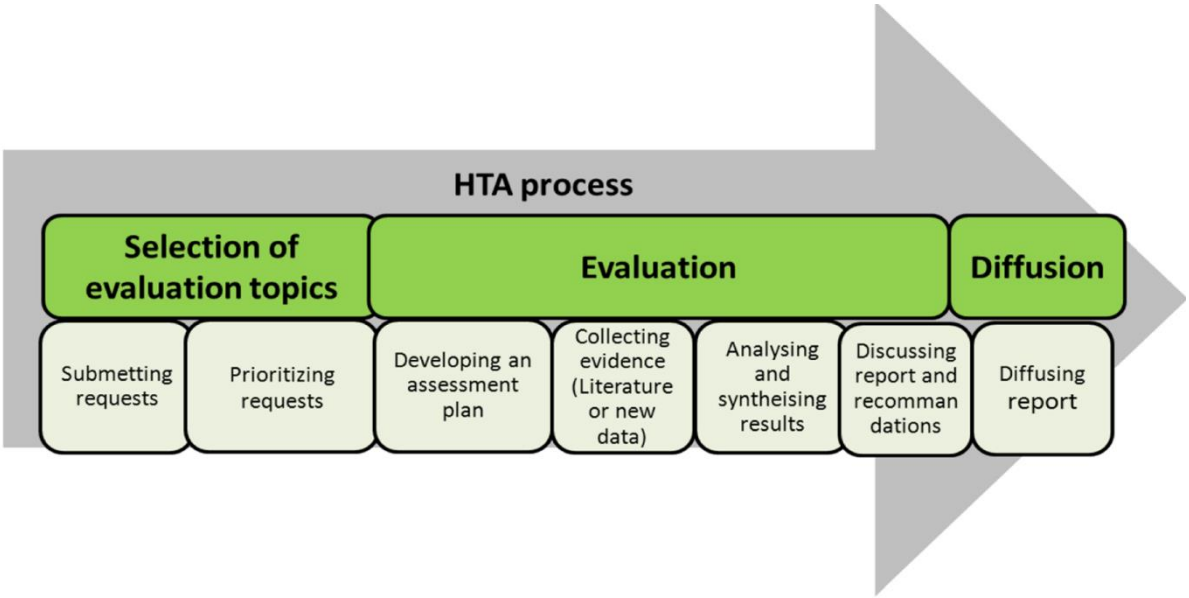


In addition to the three level, there are three stages in the HTA process outlined in this model:

Stage 1 – Selection of evaluation topics which involves submitting and prioritising requests. This is the early stage of the process, at which the authors identified a need for patients to be more actively involved in identifying topics

Stage 2 - Evaluation, which involves developing an assessment plan, collecting evidence of the literature, analysing and synthesising results and finally discussing results and recommendations.

Stage 3 diffusion - (often called dissemination), where the report is 'diffused' and shared with the public and other stakeholders.



Key elements

- Recommends that **a third of the participants involved in the deliberation process of prioritizations topics for HTA must be patients**.
- Advocates **patient involvement in all stages of the HTA process** as patient involvement in early stages make assessments 'more relevant and acceptable' (Gagnon, A015[53]).
- Claims that methods of involvement 'that involve **face-to face interaction between participants from the public and decision makers also generate greater participant satisfaction**, both in terms of process and results' (Gagnon, A015[54]).
- Based on learning from the UK, the authors suggest **patients should 'receive training** in HTA and evidence-informed healthcare before the prioritisation meetings' (Gagnon, A015[55]).
- **Patients are involved in the consultation and reviewing process** of a potential HTA topic, as well as development of the assessment plan.

Limitations

Provides limited information regarding:

- The evaluation stage, for example committees involved in consulting and reviewing evidence.
- Measuring the impact of impact of patient involvement, for example, how effective were the strategies to involve the public and did the involvement improve the process and outcomes.

This paper cites an alternative model for evaluating participation and involvement, 'Public Participation Methods: A Framework for Evaluation' (Rowe, A051)[56].

[53] https://drive.google.com/file/d/0BwQTUgazNAy5b3huQ2JWS1pwTm8
[54] https://drive.google.com/file/d/0BwQTUgazNAy5b3huQ2JWS1pwTm8
[55] https://drive.google.com/file/d/0BwQTUgazNAy5b3huQ2JWS1pwTm8

Appraisal of 'Public Participation Methods: A Framework for Evaluation' (Rowe, A051)[57]

Rowe outlines a number of 'formalised public participation models' (Rowe, A051)[58]:

Table 1. A Number of the Most Formalized Public Participation Methods

Participation Method	*Nature of Participants*	*Time Scale/Duration*	*Characteristics/Mechanism*	*Examples/References*
Referenda	Potentially all members of national or local population; realistically, a significant proportion of these.	Vote cast at single point in time.	Vote is usually choice of one of two options. All participants have equal influence. Final outcome is binding.	Biotechnology in Switzerland (Buchmann 1995); waste repository in Sweden (af Wåhlberg 1997).
Public hearings/ inquiries	Interested citizens, limited in number by size of venue. True participants are experts and politicians making presentations.	May last many weeks/ months, even years. Usually held during week-days/working hours.	Entails presentations by agencies regarding plans in open forum. Public may voice opinions but have no direct impact on recommendation.	Frequent mechanism in, for example, United States (Fiorino 1990), Australia (Davison, Barnes, and Schibeci 1997); review by Middendorf and Busch (1997).
Public opinion surveys	Large sample (e.g., 100s or 1,000s), usually representative of the population segments of interest.	Single event, usually lasting no more than several minutes.	Often enacted through written questionnaire or telephone survey. May involve variety of questions. Used for information gathering.	Radioactive sites in United States (Feldman and Hanahan 1996); genetically modified food in the United Kingdom (Vidal 1998); biotech surveys (Davison, Barnes, and Schibeci 1997).
Negotiated rule making	Small number of representatives of stakeholder groups (may include public representatives).	Uncertain: strict deadline usually set: days/weeks/ months.	Working committee of stakeholder representatives (and from sponsor). Consensus required on specific question (usually, a regulation).	Used by U.S. Environmental Protection Agency (Hanson 1984); method discussed by Susskind and McMahon (1985) and Fiorino (1990).

56

http://web.archive.org/web/20151118033233/http://www.en.ipea.gov.br/participacao/images/pdfs/participacao/2000%20public%20participation%20methods.pdf
57

http://web.archive.org/web/20151118033233/http://www.en.ipea.gov.br/participacao/images/pdfs/participacao/2000%20public%20participation%20methods.pdf
58

http://web.archive.org/web/20151118033233/http://www.en.ipea.gov.br/participacao/images/pdfs/participacao/2000%20public%20participation%20methods.pdf

Consensus conference	Generally, ten to sixteen members of public (with no knowledge on topic) selected by steering committee as "representative" of the general public.	Preparatory demonstrations and lectures (etc.) to inform panelists about topic, then three-day conference.	Lay panel with independent facilitator questions expert witnesses chosen by stakeholder panel. Meetings open to wider public. Conclusions on key questions made via report or press conference.	Used in Denmark and Netherlands on topics from food irradiation to air pollution (Joss and Durant 1994; Grundahl 1995); also used in United Kingdom on plant biotechnology (Ellahi 1995).
Citizens' jury/panel	Generally, twelve to twenty members of public selected by stakeholder panel to be roughly representative of the local population.	Not precise but generally involve meetings over a few days (e.g., four to ten).	Lay panel with independent facilitator questions expert witnesses chosen by stakeholder panel. Meetings not generally open. Conclusions on key questions made via report or press conference.	Examples in Germany, United States, and United Kingdom (e.g., Crosby, Kelly, and Schaefer 1986; Coote, Kendall, and Stewart 1994; Lenaghan, New, and Mitchell 1996).
Citizen/public advisory committee	Small group selected by sponsor to represent views of various groups or communities (may not comprise members of true public).	Takes place over an extended period of time.	Group convened by sponsor to examine some significant issue. Interaction with industry representatives.	Particularly evident in United States, for example, in cleanup of waste sites (Lynn and Busenberg 1995; Perhac 1998); see Creighton (1993) for guidelines.
Focus groups	Small group of five to twelve selected to be representative of public; several groups may be used for one project (comprising members of subgroups).	Single meeting, usually up to two hours.	Free discussion on general topic with video/tape recording and little input/direction from facilitator. Used to assess opinions/attitudes.	Guidelines from Morgan (1993); U.K. example to assess food risk (Fife-Schaw and Rowe 1995).

Evaluating the 'construction' and 'implementation' stages

In addition to outlining 'formalised public participation models', Rowe also proposes the following framework for evaluating the 'effectiveness' of the various models of participation.

Evaluation criteria are 'divided into acceptance criteria, which are related to the effective construction and implementation of a procedure, and process criteria which are related to the potential public acceptance of a procedure' (Rowe, A051)[59].

This split is justified by Rowe in the following way:

> 'If a procedure is effectively constituted but perceived by the public to be in some sense unfair or undemocratic, then the procedure may fail in alleviating public concerns. On the other hand, if a procedure and its recommendations are accepted by the public but the ultimate decision is attained in an ineffective manner, then its implementation could prove objectively damaging for sponsors and public' (Rowe, A051)[60].

The 'acceptance criteria' are:

Criterion of representativeness: The public participants should comprise a broadly representative sample of the population of the affected public.

Criterion of independence: The participation process should be conducted in an independent, unbiased way.

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[59] https://drive.google.com/file/d/0B7-zEXxcoXA4QU9hWEVNNnI0Y0U/view
[60] https://drive.google.com/file/d/0B7-zEXxcoXA4QU9hWEVNNnI0Y0U/view

Criterion of early involvement: The public should be involved as early as possible in the process as soon as value judgments become salient.

Criterion of influence: The output of the procedure should have a genuine impact on policy.

Criterion of transparency: The process should be transparent so that the public can see what is going on and how decisions are being made.

The 'process criteria' are:

Criterion of resource accessibility: Public participants should have access to the appropriate resources to enable them to successfully fulfil their brief.

Criterion of task definition: The nature and scope of the participation task should be clearly defined.

Criterion of structured decision making: The participation exercise should use/provide appropriate mechanisms for structuring and displaying the decision-making process.

Criterion of cost-effectiveness: The procedure should in some sense be cost-effective.

Results of the evaluation

Rowe provides a detailed commentary about each method and summarises the findings in the following table:

	Referenda	*Public Hearings*	*Public Opinion Survey*	*Negotiated Rule Making*	*Consensus Conference*	*Citizens' Jury/Panel*	*Citizen Advisory Committee*	*Focus Groups*
Acceptance criteria								
Representativeness of participants	High (assuming full turn-out at poll)	Low	Generally high	Low	Moderate (limited by small sample)	Moderate (limited by small sample)	Moderate to low	Moderate (limited by small sample)
Independence of true participants	High	Generally low	High	Moderate	High	High	Moderate (often relation to sponsor)	High
Early involvement?	Variable	Variable	Potentially high	Variable	Potentially high	Potentially high	Variable but may be high	Potentially high
Influence on final policy	High	Moderate	Indirect and difficult to determine	High	Variable but not guaranteed	Variable but not guaranteed	Variable but not guaranteed	Liable to be indirect
Transparency of process to the public	High	Moderate	Moderate	Low	High	Moderate	Variable but often low	Low

	Referenda	*Public Hearings*	*Public Opinion Survey*	*Negotiated Rule Making*	*Consensus Conference*	*Citizens' Jury/Panel*	*Citizen Advisory Committee*	*Focus Groups*
Process criteria								
Resource accessibility	Low	Low-moderate	Low	High	High	High	Variable	Low
Task definition	High	Generally high	Low	High	Generally high	Generally high	Variable but may be high	Variable but may be high
Structured decision making	Low	Low	Low	Moderate	Moderate (influence of facilitator)	Potentially high	Variable (influence of facilitator)	Low
Cost-effectiveness	Variable/low	Low	Potentially high	Potentially high	Moderate to high	Moderate to high	Variable	Potentially high

Key elements

Rowe proposes a framework for evaluating the 'effectiveness' of the various models of participation.

The evaluation criteria are divided into:

- Acceptance criteria - related to the effective construction and implementation of a procedure
- Process criteria - related to the potential public acceptance of a procedure

Rowe provides a detailed commentary about each method and summarises the findings.

Limitations

Rowe provides limited information regarding practical implementation of certain stages such as:

- Resource implications not addressed– although time and scale are addressed, the model doesn't compare likely resource implications such as budget. 'Cost-effectiveness' is judged, but it doesn't include staff time or expertise.
- Impact assessment – although the evaluation process for each stage is clearly articulated, there is no clear way described to measure the impact (real or perceived) of the public involvement proposed.

Appraisal of National Institute for Health and Care Excellence (NICE) process (England and Wales)

This section is a summary and appraisal of the 'Public involvement programme' (PIP) during the NICE process HTA process, published in September 2014[61]. In the interests of brevity, this report will not summarise the extensive appraisal process which can be read in full on the NICE website[62].

NICE summarises their patient and public involvement as being based on the following two principles[63]:

- that lay people, and organisations representing their interests, have opportunities to contribute to developing NICE guidance, advice and quality standards, and support their implementation, and
- that, because of this contribution, our guidance and other products have a greater focus and relevance for the people most directly affected by our recommendations

Please note, NICE divides the appraisal process into Single Technology Assessment (STA) and Multiple Technology Assessment (MTA) which, although similar processes, have slight variations in how the public are involved.

Public involvement programme' (PIP)

NICE has a 'Public involvement programme' (PIP) which 'supports and develops public involvement across NICE's work programme'[64]. NICE 'offers support throughout the appraisal process to patient and carer consultee organisations and patient experts'[65]. During the appraisal process:

> 'A PIP Public Involvement Adviser is assigned to each appraisal and supports patient and carer consultee organisations, their representatives, and individual patients or carers throughout the appraisal. The PIP public involvement adviser also supports the

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[61] http://web.archive.org/web/20151120063506/https://www.nice.org.uk/article/pmg19/chapter/3-The-appraisal-process

[62] http://web.archive.org/web/20151120063506/https://www.nice.org.uk/article/pmg19/chapter/3-The-appraisal-process#sta-initiation-and-evidence-submission

63 http://web.archive.org/web/20150304054755/http://www.nice.org.uk/about/nice-communities/public-involvement/patient-and-public-involvement-policy

64 http://web.archive.org/web/20151120082306/https://www.nice.org.uk/article/pmg19/chapter/glossary

65 http://web.archive.org/web/20151120063506/https://www.nice.org.uk/article/pmg19/chapter/3-The-appraisal-process#sta-initiation-and-evidence-submission

> lay members of the Appraisal Committees and supplies the patient and carer group information for the 'Information for the public'.'[66]

NICE has a standing Advisory Committee with people representing patient and carer organisations and lay members.

Patients Involved in NICE (PIN)

Patients Involved in NICE (PIN) is a coalition of over 80 patient organisations and 'is committed to enabling patient groups to engage productively with NICE'[67]. It is independent from NICE and the pharmaceutical industry, and members:

> 'use their combined knowledge, experience and direct contact with patients from a wide range of conditions, to ensure NICE puts patients, carers, and patient groups at the centre of all of its work. They act as a critical friend and a respected and equal partner in developing and shaping aspects of NICE's work. They provide a forum for enabling patient groups to engage with NICE, working alongside NICE's Public Involvement Programme.' [68]

Citizens Council

NICE also has a 'Citizens Council' which 'is a panel of 30 members of the public that largely reflect the demographic characteristics of the UK. Councillors are recruited by an independent organisation and serve for up to three years'[69].

The Citizens Council 'is one of the few examples of broader public engagement (as opposed to specific patients or patient advocates)' (Messina, A022)[70].

The Citizens Council 'provides NICE with a public perspective on overarching moral and ethical issues that NICE has to take account of when producing guidance. The Council's recommendations and conclusions are incorporated into a document called 'Social Value Judgements' and, where appropriate, into NICE's methodology'[71].

Operation of the Citizens Council

- Members meet once a year for 2 days at a time and their discussions are arranged and run by independent facilitators.
- The meetings are open to public observers.

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66 http://web.archive.org/web/20151120082306/https://www.nice.org.uk/article/pmg19/chapter/glossary
67 http://web.archive.org/web/20151120090653/http://www.nice.org.uk/about/nice-communities/public-involvement/pin
68 http://web.archive.org/web/20151120090653/http://www.nice.org.uk/about/nice-communities/public-involvement/pin
69 http://web.archive.org/web/20150310113938/http://www.nice.org.uk/get-involved/citizens-council
70 https://drive.google.com/open?id=0BwQTUgazNAy5WEZNN2lvejlOQkU
71 http://web.archive.org/web/20150310113938/http://www.nice.org.uk/get-involved/citizens-council

- During the meetings, Council members listen to different views from experts on a topic and undertake exercises which allow them to examine the issues in detail and thoroughly discuss their own views.
- The members' views and conclusions are captured by an independent rapporteur and the report is circulated to members for comment and amendment before finalising.
- After a meeting, the report is made available for public comment.
- A summary of these comments along with the report are then presented to NICE's board for discussion.

Significant reports by the Citizens Council

The Citizens Council produced a report in which they pose the question 'What are the societal values that need to be considered when making decisions about trade-offs between equity and efficiency?'[72]. The document concluded that 'balancing equity and efficiency is an extremely difficult exercise and that there will never be a perfect balance'[73]. The word they chose to summarise the values 'underlying' their work was 'education' as:

> 'it 'reflects underlying values, such as 'promotion of education for all' and "sowing the seeds for the future" by educating everyone to become good members of society.'

The document also states that 'A lack of good communication could lead to perceptions that values such as justice, equality and trust are not being upheld'

The following extract summarises the key values to be considered:

Key societal values to be considered across public health, social care and health care:

- Accountability
- Collective responsibility
- Dignity
- Education
- Fairness
- Honesty
- Humanity
- Individual rights
- Justice
- Maximising total benefit/benefit for most/utilitarianism
- Quality of life
- Respect
- Right to health and welfare for all
- Safeguarding the vulnerable
- Value/quality of service

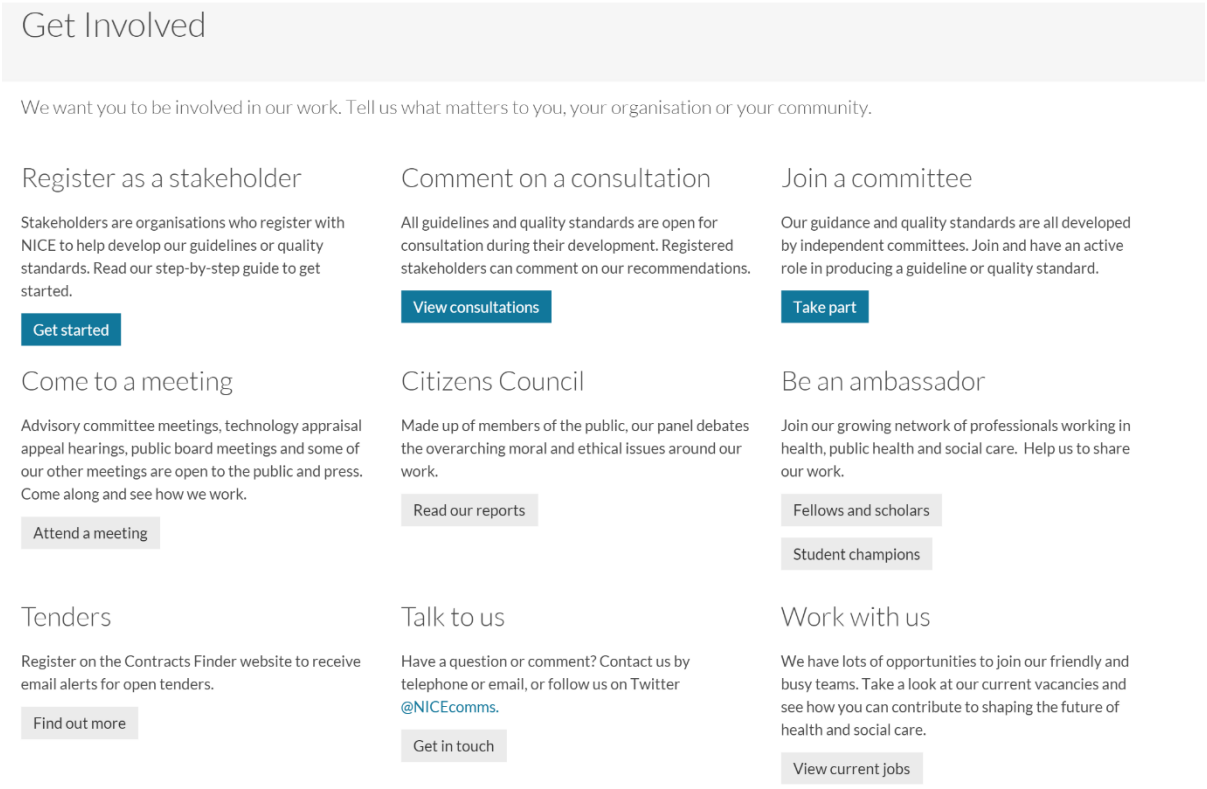
[72] http://web.archive.org/web/20151120091727/http://www.nice.org.uk/Media/Default/Get-involved/Citizens-Council/Reports/cc-report17-equity-efficiency.pdf

73 http://web.archive.org/web/20151120091727/http://www.nice.org.uk/Media/Default/Get-involved/Citizens-Council/Reports/cc-report17-equity-efficiency.pdf

This extract contains the prioritised values from public health discussions:

Ways of getting involved

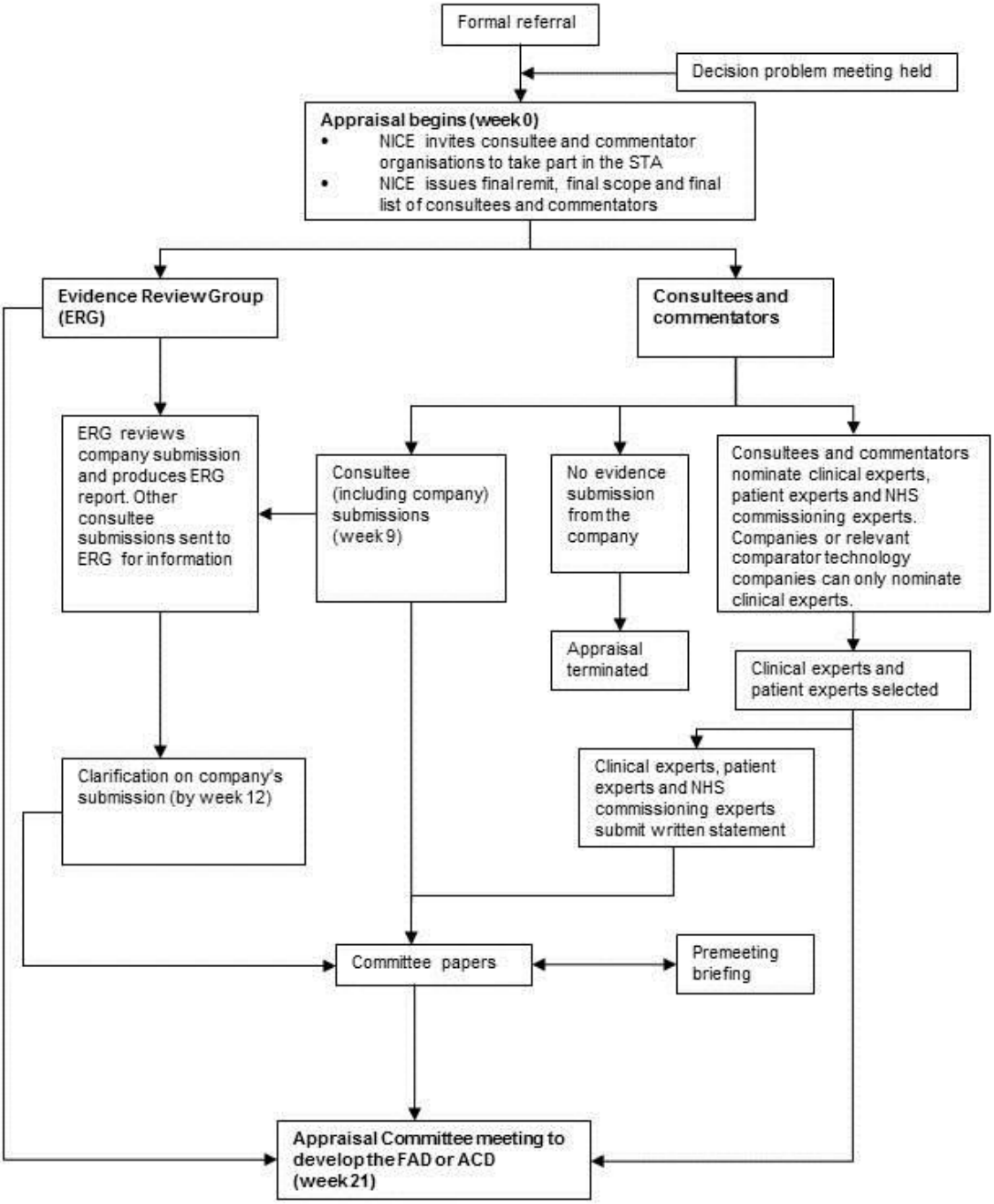
NICE clearly presents the ways that the public can be involved, including some of the ways outlined above[74]:



A more complex explanation of the appraisal process (including where the public can be involved) is given for both the Single Technology Assessment (STA) and the Multiple Technology Assessment (MTA).

[74] http://web.archive.org/web/20151120114236/http://www.nice.org.uk/get-involved
This document was created by Jack Nunn for the Consumer Health Forum on 11 October 2016. To give feedback, send an email or contact @JackNunn.

Here is an extract from the STA process (the full processes can be found on the NICE website)[75]:



NICE in Australia

The Government of Western Australia achieved accreditation from NICE International for the process used to produce its Diagnostic Imaging Pathways (DIP) in April 2012[76].

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[75] http://web.archive.org/web/20151120063506/https://www.nice.org.uk/article/pmg19/chapter/3-The-appraisal-process#sta-initiation-and-evidence-submission

Key elements

- Appraisal committee meetings are open to the public, which promotes public understanding of how evidence is assessed.
- The Public Involvement Programme (PIP) assigns a Public Involvement Adviser to each appraisal and supports patient and carer consultee organisations, their representatives, and individual patients or carers throughout the appraisal.
- When STA are taking place, Appraisal Consultation Document(s) (ACD) are published on the NICE website to allow access to the public, (including experts from different fields), to submit their comments. A lay version of the ACD for the public, known as 'Information for the public') is published on its website. This inclusive process allows for different perspectives to be denoted and published for the Advisory Committee to take into account.
- The public can appeal recommendations
- The Citizens Council 'is one of the few examples of broader public engagement (as opposed to specific patients or patient advocates)' (Messina, A022)[77].
-

Limitations

Despite a considerable amount of information being placed online during the appraisal process, there are no online learning, training or development resources for public audience, in particular regarding how to assess evidence, and how to produce a proper written submission or proposal.

76 http://web.archive.org/web/20151120064212/https://www.nice.org.uk/about/what-we-do/accreditation/case-studies/government-of-western-australia
77 https://drive.google.com/open?id=0BwQTUgazNAy5WEZNN2IvejlOQkU

Other significant models

Canadian Agency for Drugs and Technologies in Health (CADTH)

The Canadian Agency for Drugs and Technologies in Health states that:

> 'Listening to patients is a vital part of CADTH's work. We recognize that patients have unique knowledge about what it is like to live with a specific disease or medical condition. They can describe advantages and disadvantages of current therapies, which may not be reported in published literature. And they can tell us what they would most value from a new treatment'[78].

They also recognise 'stakeholders' as 'individuals and organizations — with important insights to contribute to our work'. In order to 'capture all of this evidence' they have two ways of involving the public:

- Input is solicited at the outset of a project and is usually reserved for patient groups.
- Feedback is requested after an initial recommendation or draft report has been produced. Eligibility to provide feedback varies depending on the CADTH product, but it is often open to anyone with an interest in the work.

Access to outpatient prescription drugs is 'secured through public and/or private insurance plans, with the federal, provincial, and territorial governments offering varying levels of coverage, with different eligibility requirements, premiums, and deductibles' (Messina, A022)[79]. The Common Drug Review (CDR) 'makes recommendations for formulary listing of new drugs to the 18 participating publicly funded drug plans', with recommendations 'based on the effectiveness, safety, and cost effectiveness of the medication under review compared with existing therapies (including non-drug therapies)' (Messina, A022)[80].

[78] http://web.archive.org/web/20151124003854/https://www.cadth.ca/provide-input
[79] https://drive.google.com/open?id=0BwQTUgazNAy5WEZNN2lvejlOQkU
[80] https://drive.google.com/open?id=0BwQTUgazNAy5WEZNN2lvejlOQkU

Below is an extract from the website which summarises ways of getting involved[81]:

CADTH Common Drug Review Patient Group Input

The CADTH Common Drug Review (CDR) undertakes rigorous, objective reviews of drugs and provides formulary listing recommendations to Canada's publicly funded health plans (except Quebec).

CDR Input →

CADTH Pan-Canadian Oncology Drug Review Patient Group Input and Feedback

The CADTH pan-Canadian Oncology Drug Review (pCODR) undertakes rigorous, objective reviews of cancer drugs and makes funding recommendations to Canada's provinces and territories (except Quebec).

pCODR Input/Feedback →

Other Stakeholder Feedback

CADTH produces a variety of different types of reports related to health technologies, including prescription drugs and medical devices. CADTH frequently invites feedback on this work from interested parties.

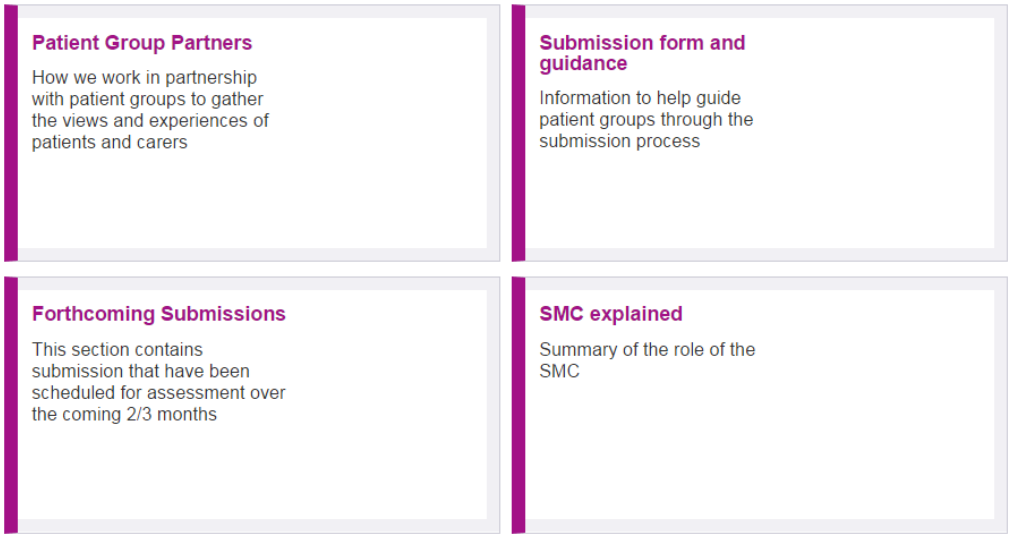
[81] http://web.archive.org/web/20151124003854/https://www.cadth.ca/provide-input
This document was created by Jack Nunn for the Consumer Health Forum on 11 October 2016. To give feedback, send an email or contact @JackNunn.

Scottish Medicines Consortium

The Scottish Medicines Consortium (SMC) has a webpage titled 'public involvement', but doesn't use the term public on the page, with the heading 'Capturing the patient and carer voice[82]':

> Understanding the experiences of **patients, their families and carers** is a key element in our decision making process. It is important for SMC members to fully understand how a new medicine impacts the quality of life of patients and carers. This enables them to make a fully informed decision on whether or not to recommend a new medicine. **Patients, members of their families and carers can provide unique knowledge** about what it's like to live with a condition. They can explain advantages and disadvantages of medicines that may not be available in the published literature or quality of life measures. **We work in partnership with patient groups** to gather this information through our patient group submissions.

Below is an extract from their webpage which summarises ways of getting involved[83]:



The SMC also has a 'Public Involvement Network' (PIN) which is 'made up of patient and carer groups who use their knowledge, experience and direct contacts with patients and carers to ensure the views of patients, carers and members of the public are captured and used to inform SMC processes'. SMC states that:

> The PIN Advisory Group helps SMC to continuously improve how we involve patients, carers and members of the public in our work. Membership includes four PIN patient

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82 http://web.archive.org/web/20151124004918/https://www.scottishmedicines.org.uk/Public_Involvement/Public_Involvement

83 http://web.archive.org/web/20151124004918/https://www.scottishmedicines.org.uk/Public_Involvement/Public_Involvement

group partners, each of whom has active contact with patients and carers and previous experience of submitting to SMC. To make sure we have a wide range of representation in the group, one representative is nominated through each of the following umbrella organisations: Scottish Cancer Coalition, Alliance, Genetic Alliance UK and Carers' Trust. The group also includes all SMC Public Partners and some members of the SMC team, including an Area Drug and Therapeutics Committee (ADTC) representative and an SMC committee member.

According to the terms of reference, the purpose of the advisory group is to 'strengthen future public involvement and encourage patient groups to participate in' the work of the SMC[84].

The SMC also has 'three public partners who are volunteer members of the public working as part of SMC Public Involvement team'[85]. They are also full voting members of the SMC committee and their role is to 'help ensure that the views of patients, carers and members of the public are taken into account during all SMC decision making processes'.

The public partner has a variety of responsibilities which include:

- Preparing a presentation of patient group submissions which accurately highlights key issues and presenting these submissions during monthly SMC committee meetings.
- Reading SMC committee papers in advance of attending monthly SMC meetings in order to be able to make an informed decision as a voting member of SMC.
- Participating in Patient and Clinician Engagement (PACE) meetings to help ensure that patient and carer perspectives are fully explored and discussed during the PACE meeting and that the views of the expert advisors in attendance are appropriately reflected in the resulting PACE documentation.

SMC committee meetings are 'open for members of the public to observe'[86].

84
http://web.archive.org/web/20151124005916/https://www.scottishmedicines.org.uk/Public_Involvement/PIN_Advisory_Group_Terms_of_Reference.pdf
85
http://web.archive.org/web/20151124010226/http://www.scottishmedicines.org.uk/Public_Involvement/SMC_explained/Public_involvement_within_SMC
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http://web.archive.org/web/20151124010226/http://www.scottishmedicines.org.uk/Public_Involvement/SMC_explained/Public_involvement_within_SMC

Relevant generic models of involvement

This section contains a summary of models of public involvement and engagement which, while relevant to health technology assessment, are more generic.

Please note, when referring to models which use the word 'consumer', this section will use that language to reflect the models being described.

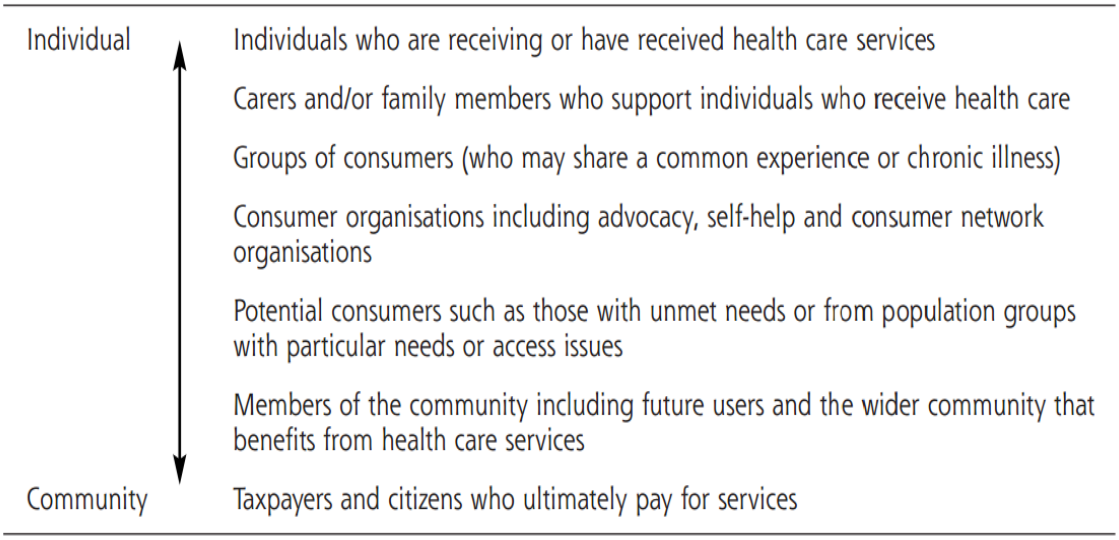
Understanding whose voices need to be heard

It is important to acknowledge that a number of voices need to be heard to ensure that the perspectives of as many people as possible are incorporated in an organisation seeking the views of the public.

Similarly, it is important to acknowledge the 'screaming silences' from people who may be unintentionally marginalised[87].

Several studies have explored this idea. For example, a consumer participation resource guide for organisations, produced by the Department of Public Health and Flinders University in the early 2000s, proposed a continuum of voices from the individual to the community voice[88]. See Figure 1 below.

Figure 1: Voices



87 http://web.archive.org/web/20151126060635/http://jrn.sagepub.com/content/early/2010/11/11/1744987110387741

88 http://web.archive.org/web/20151120041252/http://healthissuescentre.org.au/images/uploads/resources/Improving-health-services-through-cp-resources-guide-for-orgs.pdf

The guide explains that:

> As you move down the list, the focus spreads outward from the individual and comes to effectively embrace the whole community. For this reason consumer participation at these broader levels is also referred to as community participation. All these voices have a potential contribution to make through involvement in your health care organisation. Consumers are diverse, but be aware that participation approaches can sometimes be limited to ways that appeal to certain ethnic and socio-economic groups only. (Department of Public Health, Flinders University, and the South Australian Community Health Research Unit, p.4)

The guide also includes 'The ladder of participation', which is a useful way of locating the degree of control the public have over a process, for example, the MBS Review:

Degree	Participants' action	Illustrative mode
High ↑	Have control	Organisation asks community to identify the problem and to make all the key decisions on goals and means. Willing to help community at each step to accomplish goals.
	Have delegated	Organisation identifies and presents a problem to the community, defines the limits and asks community to make a series of decisions, which can be embodied in a plan it can accept.
	Plan jointly	Organisation presents tentative plan subject to change and open to change from those affected. Expects to change plan at least slightly and perhaps more subsequently.
	Advise	Organisation presents a plan and invites questions. Prepared to modify plan only if absolutely necessary.
↓ Low	Are consulted	Organisation tries to promote a plan. Seeks to develop support to facilitate acceptance or give sufficient sanction to plan so administrative compliance can be expected.
	Receive information	Organisation makes a plan and announces it. Community is convened for informational purposes. Compliance is expected.
	None	Community not involved.

Cancer Australia, in their National Framework for Consumer Involvement in Cancer Control (2012: 11-12), emphasise the need to identify whose voices need to be heard., Cancer Australia developed a typology of the consumer voice and the roles consumers assume when engaging with a health service or organisation. For example, consumers may be asked to participate in a focus group or tell their story, a role relating to their *personal* engagement in treatment or managing their illness and what the organisation can learn from this.

On other occasions, consumers may engage as *advocates* on behalf of a range of people affected by cancer. Or they may be asked for their views as *advisors* or *experts* due to their level of knowledge of issues concerning people affected by cancer. Alternatively, they may be

asked as *partners* based also on their key knowledge of the health system as an end-user. See Figure 2 below.

Figure 2: Typology on the consumer voice, Cancer Australia

Another model is from the Health Research Authority in the UK; it has published a statement about public involvement in research[89]. This may be useful to understand whose voices need to be heard and in which circumstances. For example, some researchers, health services or organisations would benefit from involving the public in general – precisely because they are not affected by a specific health condition. On other occasions, they may require the involvement of people affected by a specific condition, those who provide unpaid care or have an experience or relationship with a person affected by a health condition. Finally, they may benefit from partnerships with health condition-specific consumer groups, community groups or charities.

[89] http://web.archive.org/web/20151120041757/http://www.hra.nhs.uk/documents/2013/10/hra-public-involvement-strategy-circulation-september-2013.pdf

Here is an extract from the Health Research Authority Statement:

Appendix A: What do we mean by public involvement in health research?

A1 By **public involvement** we mean a range of activities that enable patients and the public to have a say in decisions about the way health research is planned, designed, delivered, developed, evaluated, managed and regulated. It also means where patients and the public are actively involved in the conduct of research studies.

A2 **Public involvement** means that work is undertaken 'with' or 'by' patients and the public rather than 'to', 'about' or 'for' them.

A3 By **public involvement** we do not mean **participation**, where people are recruited to and take part in research studies as the subjects of the research, and contribute the information or data used to answer the question being addressed.

A4 We recognise that other people and organisations use a range of terms for what we refer to as **public involvement** in their own activities, including **public engagement** and **public participation**. However, we have decided to use the term **public involvement** for this to be consistent with the Department of Health, National Institute for Health Research (NIHR) and majority of organisations who fund and manage health research in the UK.

A5 We will use the term **public involvement** as a short-hand term for involving patients and the public in health research. When we use this term **public** means patients, potential patients or members of the public including those with known genetic dispositions, carers and people who use health and social care services as well as people from organisations that represent people who use health and social care services.

A6 Where necessary we will define what we mean by **public** depending on who is taking part in the involvement activity. For instance, there may be times when patients and the public are involved, or where what is needed is the general public and not patients, or other times where patients and carers are needed and not the general public.

A7 We will not use any abbreviations for public involvement, such as PPI (for Patient and Public Involvement). This is to ensure that it is always clear that we mean **involvement** and that it is about patients and the public. It will also help avoid developing a jargon term that is misused, for example "PPI people", "PPI involvement", "PPI-ing".

A8 The way in which patients and the public can be involved in the work of organisations varies. Different methods need to be used appropriate to the circumstances and audiences, which can vary in depth, influence, and timescale.

National and international frameworks

There are several national and international frameworks for 'Patient Centred Care', 'public involvement', 'citizen involvement' and 'consumer engagement'.

Institute for Patient and Family- Centered Care (US)

The best-known practice model in terms of Patient Centred Care (PCC) is from the Institute for Patient- and Family- Centered Care (US).

While this model is targeted at the delivery of care, the principles of involvement (respect, information sharing, participation and collaboration) are highly transferable to the HTA process, with pertinent points highlighted in **bold**.

'Advancing the Practice of Patient- and Family-centred Care in Primary Care and Other Ambulatory Settings' is a guide for primary care and other ambulatory settings. The Institute outlines a framework, which includes four core concepts of PCC, and a series of recommendations for health services hoping to embed PCC in their practice[90]. While the focus is on patient-centred care, it has significant relevance to the MBS. Significant parts of this model are summarised below.

The four core concepts or principles of PCC are:

1. Respect and dignity
2. Information sharing
3. Participation
4. Collaboration

1. How to embed dignity and respect into practice?

- clinicians and staff individualise care considering patient and family goals, priorities and values
- care and referrals are coordinated across departments and specialists.
- **staff understand, and position descriptions include, the value of a patient centred approach to health care**
- **staff with skills and attitudes aligned with patient centred care are employed by the health service**
- **staff training includes communication skills and patient centred care principles and practice**
- **patient and family experiences of care are collected systematically and analysed for quality improvement (e.g. using storytelling, interviews, recordings, video clips, writing, visual arts, etc.)**

[90] http://web.archive.org/web/20151120042447/http://www.ipfcc.org/pdf/GettingStarted-AmbulatoryCare.pdf

- families are welcome to be with the patient as much as the patient chooses
- visiting hours (for non-family members) are flexible and take into consideration patient and family preferences
- there are strategies to address the cultural diversity of patients and families (e.g. cultural awareness training, getting to know your community workshops, interpreters, etc.)
- patients and families are involved in the design of facilities to respect diversity, privacy and comfort; they feel welcomed into the health service (e.g. clear signage, parking)

2. How to embed information sharing into practice?

- patients and families receive timely and clear information about medications, lab reports, x-rays and other tests (e.g. using medication lists and hand-held medical and clinical records)
- information is provided in formats, media, language and reading levels appropriate to the patients and families
- patients and families are involved in the review and development of information (written, web-based, DVDs, etc.)
- the health service uses a well-written health information guide when producing information for patients and families (e.g. Victorian Department of Health 'Well-written health information guide')

3. How to embed participation in practice?

- patient and families are seen as essential members of the heath care team
- family members are encouraged and supported to be involved in care planning, decision-making about care and treatments and discharge processes
- patients and families are encouraged to be present and participate in rounds and nurse shift changes

4. How to embed *collaboration* into practice?

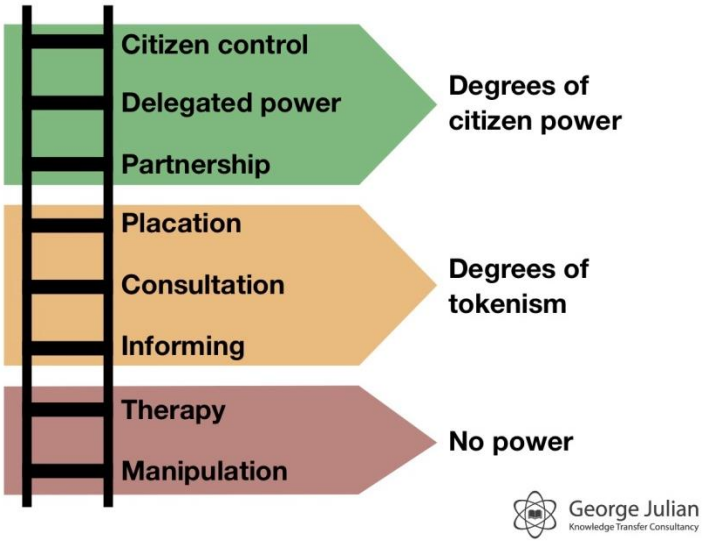
- clinicians, staff and leadership of the organisation support a patient centred, collaborative approach and welcome working in collaboration with patients and families in:
  - governance (e.g. Board, executive team)
  - committees and teams (e.g. safety and quality, ethics, research, buildings and grounds, catering)
  - professional development (e.g. training for staff)
  - staff selection and performance appraisals
  - review of complaints and compliments processes
  - review of health information
- patients and families involved in collaborative initiatives (committees and teams) receive support and training (e.g. reimbursement for out-of-pocket expenses, timely agendas and minutes, briefing and debriefing, orientation, skills development opportunities, acknowledgement of contributions, etc.)
- patients and families establish an advisory group for the health service and receive support from the health service (e.g. administrative, secretariat, reimbursement for out-of-pocket expenses, peer support, mentoring, etc.)

- the health service has systems and processes in place to support collaboration (e.g. policy, staff employed to lead and support the collaboration, annual budget allocation, evaluation). (Institute for Patient- and Family- Centered Care, 2011)

The 'ladder of citizen participation'

The 'ladder of citizen participation' was developed in the late 1960s by Sherri Arnstein[91]. She envisaged eight levels of citizen participation. Please note, this report has produced an updated, action-based model in the section 'Social determinants of involvement'.

Figure 3: Ladder of citizen participation, Sherri Arnstein[92]



The levels of participation are:

- *Manipulation* and *Therapy* are both non-participative; the aim of these interventions is to cure or educate the participants or to achieve public support by public relations.

- *Informing* is a most important first step to legitimate participation, but too frequently the emphasis is on a one way flow of information, there are no channels for feedback.

- *Consultation* is a legitimate step and includes, for example, attitude surveys, neighbourhood meetings and public enquiries.

91 https://www.planning.org/pas/memo/2007/mar/pdf/JAPA35No4.pdf
92 http://web.archive.org/save/http://www.georgejulian.co.uk/2013/01/22/social-media-and-citizen-engagement/

- *Placation*, for example, co-opt and hand-pick community members onto committees; it allows citizens to advise or plan, but the power-holders retain the right to judge the legitimacy or feasibility of the advice.

- *Partnership* implies that the power is in fact redistributed through negotiation between citizens and power holders; the planning and decision-making responsibilities are shared, e.g. through joint committees.

- *Delegated power* implies that citizens hold a majority of seats on committees and have delegated powers to make decisions. Public now has the power to assure accountability of the programs.

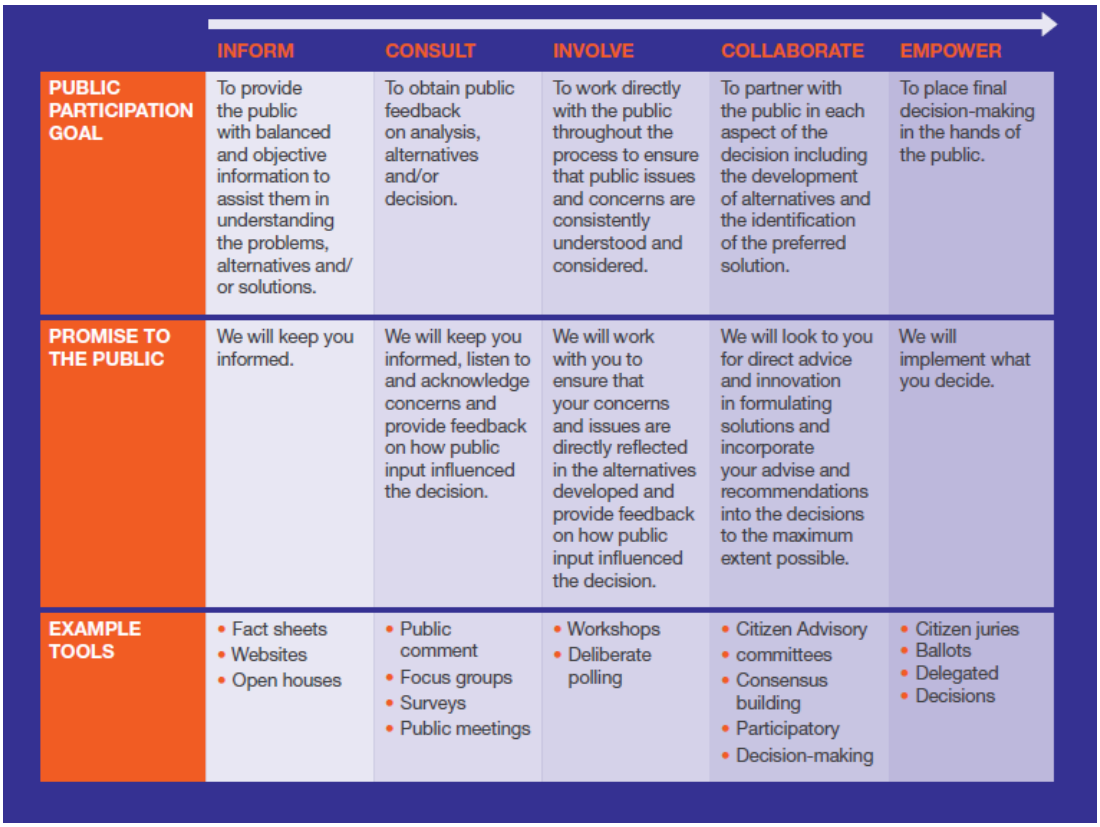
- *Citizen Control* is when the have-nots handle the entire job of planning, policy making and managing a programme, e.g. neighbourhood corporation with no intermediaries between it and the source of funds. (Arnstein S 1969)

The International Association for Public Participation

The International Association for Public Participation (IAP2) developed a public participation spectrum[93], which reworks the traditional 'ladder of participation'. It is widely used in urban planning and by councils and municipalities in planning in collaboration with citizens in their catchments. Although not specific to the health sector, the spectrum of participation is useful for all public services, including health services and organisations in the health sector. It divides the 'spectrum of participation' into 'goals' and 'promises' and gives examples of tools which can be used to achieve these.

[93] http://web.archive.org/save/https://www.iap2.org.au/resources/iap2s-public-participation-spectrum

Figure 4: IAP2 public participation spectrum, International Association for Public Participation [94]



	INFORM	CONSULT	INVOLVE	COLLABORATE	EMPOWER
PUBLIC PARTICIPATION GOAL	To provide the public with balanced and objective information to assist them in understanding the problems, alternatives and/or solutions.	To obtain public feedback on analysis, alternatives and/or decision.	To work directly with the public throughout the process to ensure that public issues and concerns are consistently understood and considered.	To partner with the public in each aspect of the decision including the development of alternatives and the identification of the preferred solution.	To place final decision-making in the hands of the public.
PROMISE TO THE PUBLIC	We will keep you informed.	We will keep you informed, listen to and acknowledge concerns and provide feedback on how public input influenced the decision.	We will work with you to ensure that your concerns and issues are directly reflected in the alternatives developed and provide feedback on how public input influenced the decision.	We will look to you for direct advice and innovation in formulating solutions and incorporate your advise and recommendations into the decisions to the maximum extent possible.	We will implement what you decide.
EXAMPLE TOOLS	• Fact sheets • Websites • Open houses	• Public comment • Focus groups • Surveys • Public meetings	• Workshops • Deliberate polling	• Citizen Advisory committees • Consensus building • Participatory Decision-making	• Citizen juries • Ballots • Delegated Decisions

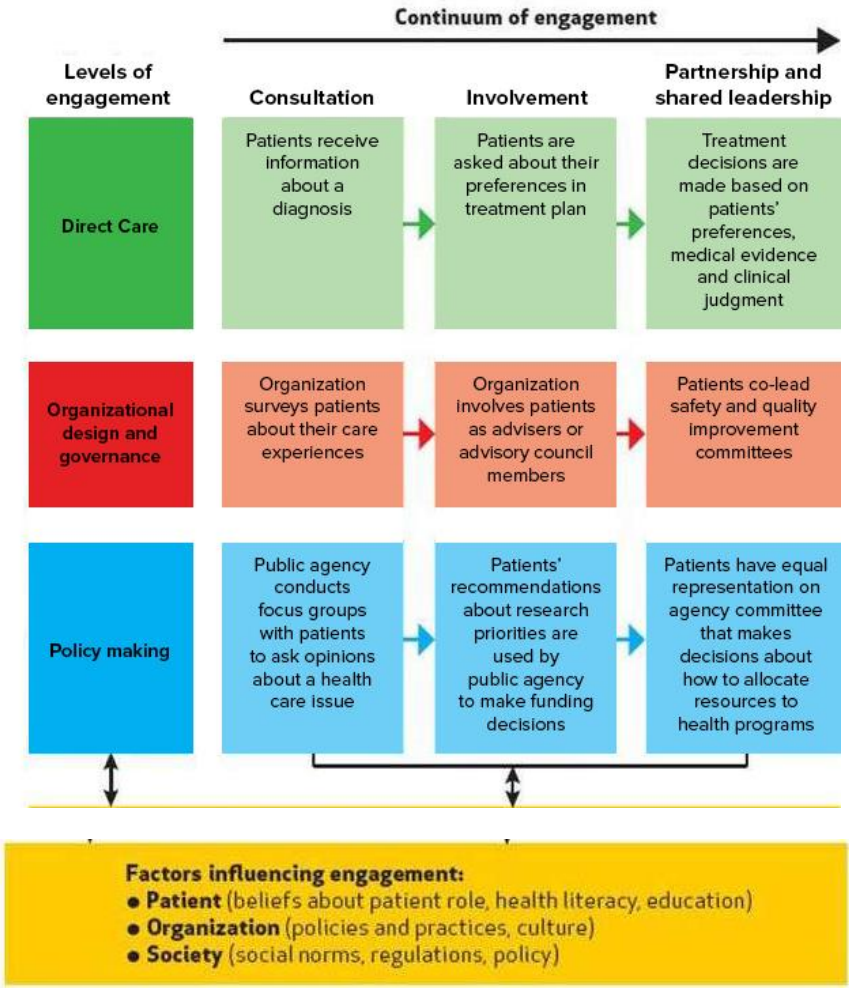
Patient and Family Engagement (PFE) Framework

The American Institute for Research developed the Patient and Family Engagement (PFE) Framework as an instrument to help drive actions toward outcomes[95]. These outcomes are: better health outcomes, improved population health, better health care quality, cost-effective care, and a more patient centred healthcare system. The PFE Framework shows how the role of patients and families can be expanded across all critical areas of health care: at the point of care, in health care organisations, and in policy-making. See Figure 5 below.

[94] http://web.archive.org/save/https://www.iap2.org.au/resources/iap2s-public-participation-spectrum

95 https://web.archive.org/web/20151126040401/http://aircpce.org/model-patient-family-engagement/

Figure 5: PFE Framework, American Institute for Research[96]

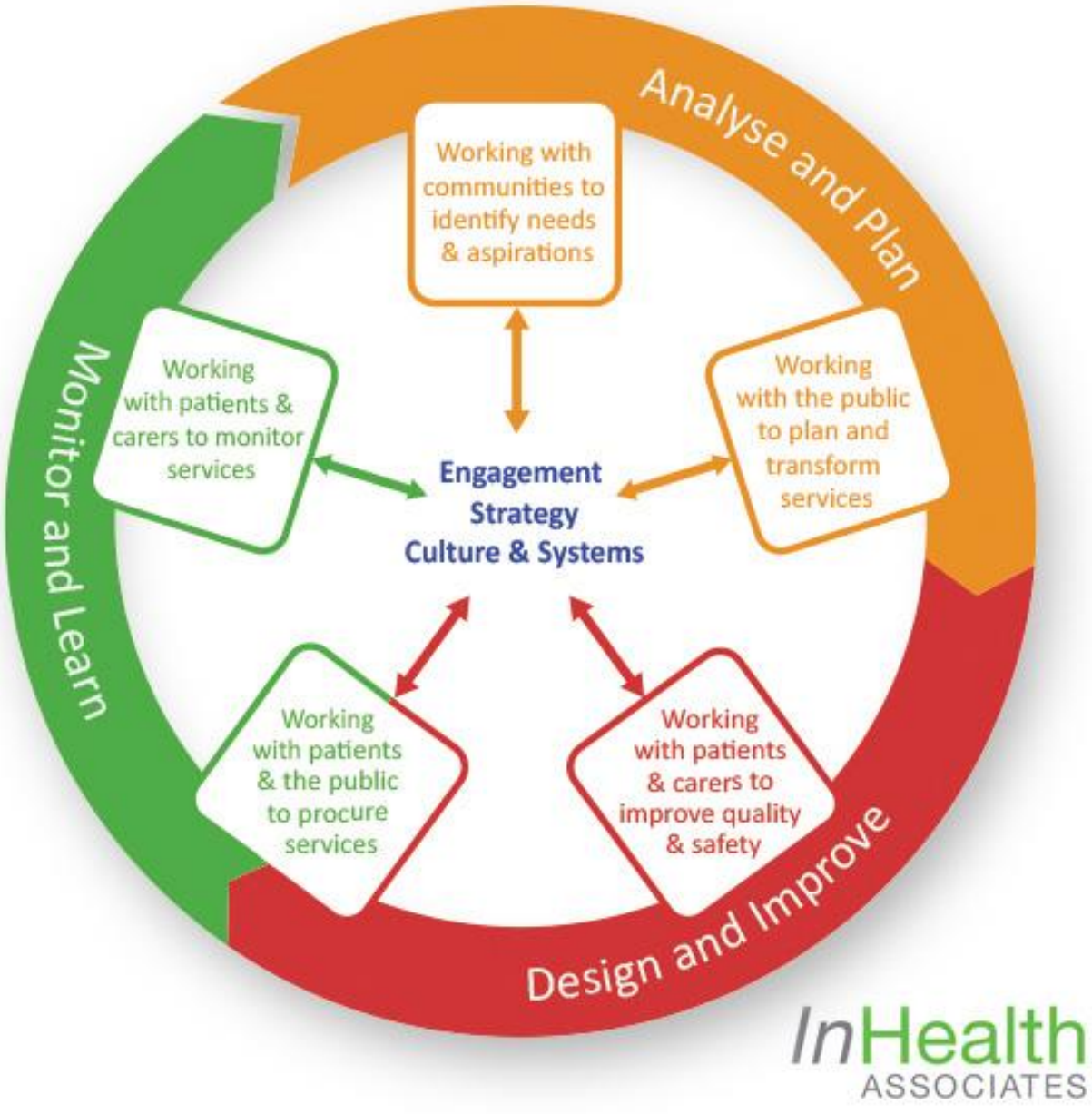


[96] https://web.archive.org/web/20151126040401/http://aircpce.org/model-patient-family-engagement/

This document was created by Jack Nunn for the Consumer Health Forum on 11 October 2016. To give feedback, send an email or contact @JackNunn.

The Engagement Cycle

InHealth Associates is a UK network of patient centered improvement specialists and experienced patient and public engagement practitioners. They developed the 'Engagement Cycle' as a useful model to use for planning and developing an engagement and involvement strategy[97].



There are ten key elements of the 'Engagement cycle':

97 https://web.archive.org/web/20150114024258/http://engagementcycle.org/engagement-strategy-culture-and-systems/

1. Be clear on the vision and build shared understanding
   The model can contribute towards a shared understanding of what engagement means, its different purposes and benefits. It helps develop the principles underpinning a vision, strategy and plans for local engagement.
2. Develop an engagement strategy that links to other work
   The Engagement Cycle can be used as the basis for developing a strategy on engagement and should be linked to other organisational plans.

3. Be clear about who needs to do what
   Roles and responsibilities for engagement at strategic and operational level need to be clear. This includes management, Boards, lay members, team leaders, and community members.

4. Embed engagement in governance arrangements
   The Board requires processes to ensure that information gained from engagement is used to provide insight (into current services) and foresight (for strategic planning).

5. Ongoing mentoring and evaluation
   An assessment of engagement activities (outcomes, processes, mechanisms) should be undertaken for each stage of the cycle. Involve patients, carers and the public in gathering data, analysing it, and in decisions about what happens next.

6. Develop meaningful engagement structures
   Think 'function before form' and build on what already exists. Any structure (e.g. consumer advisory group) should have clear purposes. Use consultation and engagement mechanisms such as those described in the Participation compass.

7. Build trusting relationships
   At each stage of The Engagement Cycle, it is crucial to develop dialogue with local patient and community organisations and patient leaders. Take every opportunity to build links with local people and groups – be ready to 'walk the talk' and be able to explain clearly what you are doing.

8. Provide adequate resources

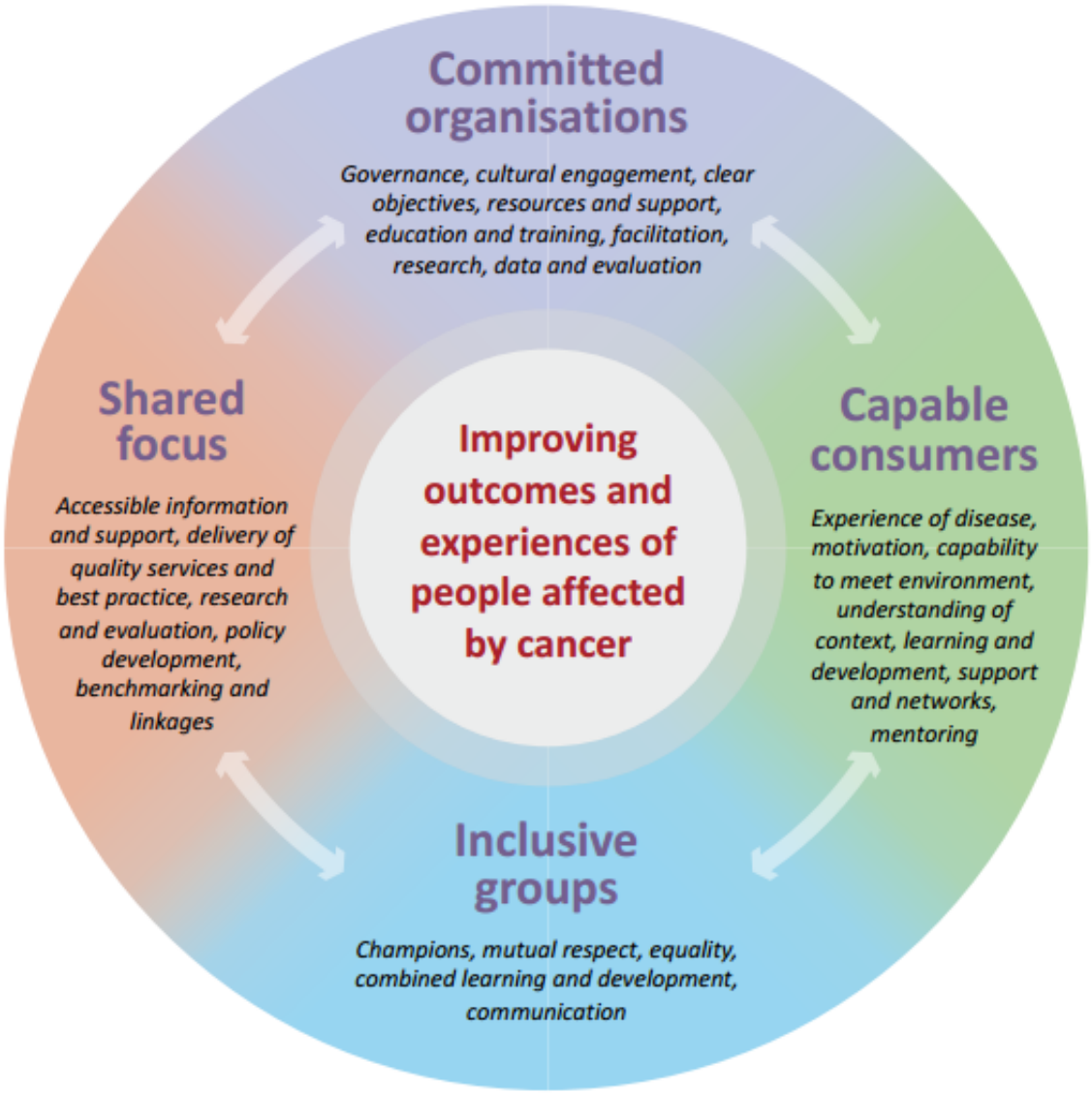
- To move engagement from a 'nice to have' to a 'must do' means providing sufficient resources for engagement within operational programs and team budgets. This includes payment, reimbursements, acknowledgements and incentives for patients and the public, as well as investment in training and support.

9. Provide learning and support to staff
   Different people require learning and support in order to implement The Engagement Cycle. It is important to think through who needs learning and support in order to develop confidence, and skills in this area, for example Board members, team leaders, health professionals and clinical staff.

10. Provide learning and support to patients, carers and the public
    Providing learning and support for patients and the public is crucial. There are many sorts of patient leaders who also need opportunities to build their capacity to engage in dialogue, be effective and build trusting relationships.

Framework for Consumer Involvement in Cancer Control

Cancer Australia developed its Framework for Consumer Involvement in Cancer Control in 2011 which includes four main key elements[98].



Below is a summary of each group identified by the model.

Committed organisations: Committed organisations integrate consumer involvement throughout every level of their organisation, service or group. Organisations which are committed to involving consumers demonstrate the following:

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98 http://web.archive.org/web/20151126041346/https://canceraustralia.gov.au/sites/default/files/publications/national_consumer_framework_web_504af020f2184.pdf

- governance: a governance structure which incorporates principles, values and elements of consumer participation
- cultural engagement: active involvement of people with respect to their cultural needs, and targeted approaches aimed at those culturally diverse communities whose outcomes are poorer
- clear objectives: consumer involvement which has clear objectives in Terms of Reference, policies and procedures
- resources and support: consumers are explicitly resourced and supported to be effectively engaged
- education and training: consumers are provided with appropriate training and development opportunities; staff are trained to strengthen their understanding of the benefits of consumer involvement
- facilitation: active facilitation and coordination of consumer involvement activities, including consumer feedback and participation in organisational strategy
- research, data and evaluation: consumer involvement activities are monitored; involvement strategies are researched and evaluated for quality improvement and benchmarking.

Capable consumers: Capable consumers have developed knowledge from their experience and are able to represent the views of others. The key characteristics of a capable consumer are:

- consumer experience: consumers have an experience of cancer either as a patient, carer, family member or survivor
- consumer motivation: consumers are motivated to participate in a largely voluntary role to improve outcomes for others
- consumer capability to meet the environment: consumers develop their skills and capabilities to meet the requirements of the role
- consumer understanding of context: consumers develop an understanding of the health context where they are involved, and the types of consumer involvement
- learning and development: consumers undertake learning and development opportunities, including conference and forum attendance and co-authoring journal articles, to build their expertise in consumer participation
- consumer support and networks: consumers seek support through connections with consumer organisations, networks and support groups
- consumer mentoring: consumers encourage and support other consumers to actively participate and develop in the role of consumer representative

Inclusive groups: to gain the most out of consumer participation it is important to cultivate an environment where consumers feel valued and equal members with others in the group. This environment can best be identified as an 'inclusive group'. Inclusive groups which are committed to involving consumers demonstrate the following:

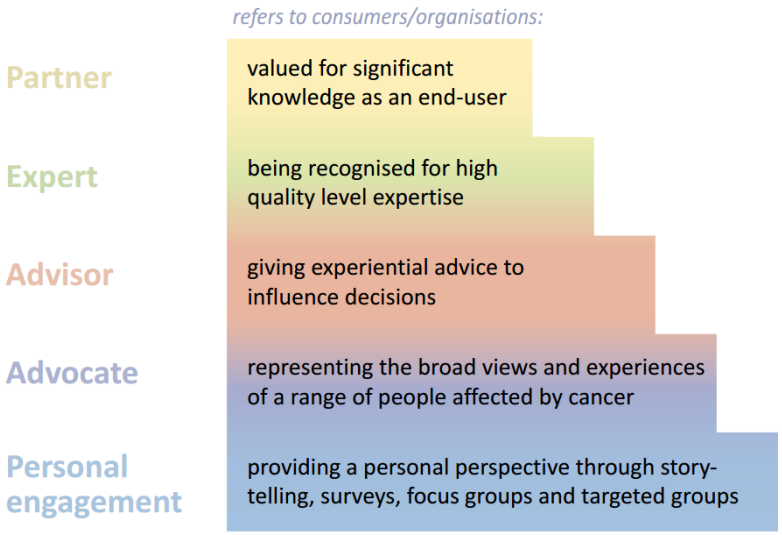
- champions: leaders exist within the organisation who promote the benefits of consumer involvement
- mutual respect: consumers are respected and valued for their contribution. Their views are actively sought, listened to and considered.
- equality: consumers are considered equal members of the team

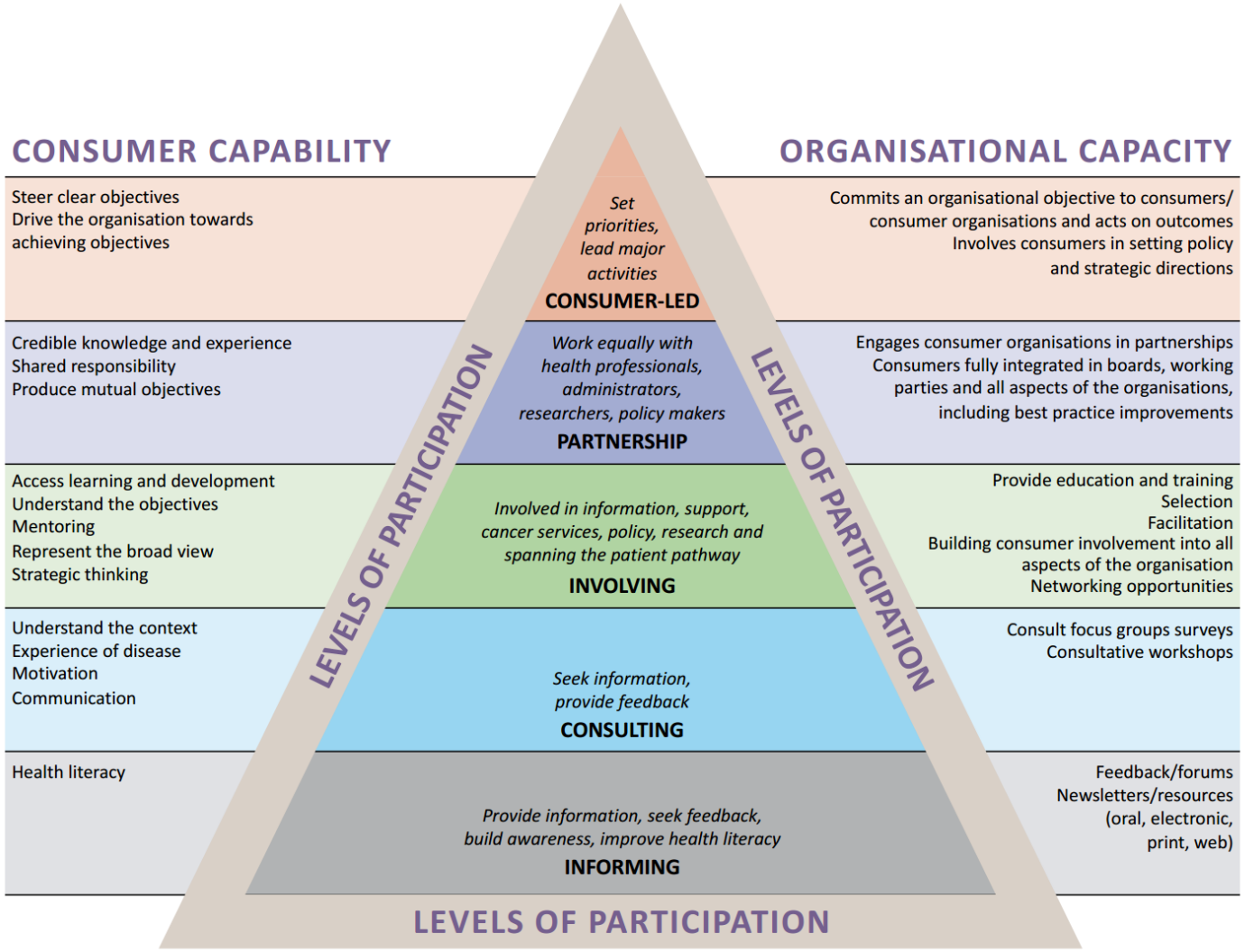
- combined professional development: professionals and consumers undertake professional development opportunities together and learn from each other's knowledge and experience
- communication: professionals and consumers communicate in a way that builds knowledge, understanding and mutual respect.

Shared focus: This element means that to have effective consumer involvement in cancer control, consumers are active participants, actively supported by organisational systems and processes, working as members of a team to achieve objectives. This element draws all elements together to focus on outcomes. In order to have a shared focus, consumers may be actively involved in the following areas:

- development of accessible information and support: working together, consumers and professionals develop accessible information and support for people affected by cancer
- delivery of quality services and best practice: consumers join with health professionals to ensure the delivery of safe and high quality cancer services based on best practice
- research and evaluation: consumers are involved in the design, conduct, translation and evaluation of research
- policy development: consumers participate in policy development to improve cancer outcomes
- benchmarking and linkages: consumers and professionals develop performance measures to help determine the effectiveness of consumer involvement and facilitate benchmarking opportunities for quality improvement.

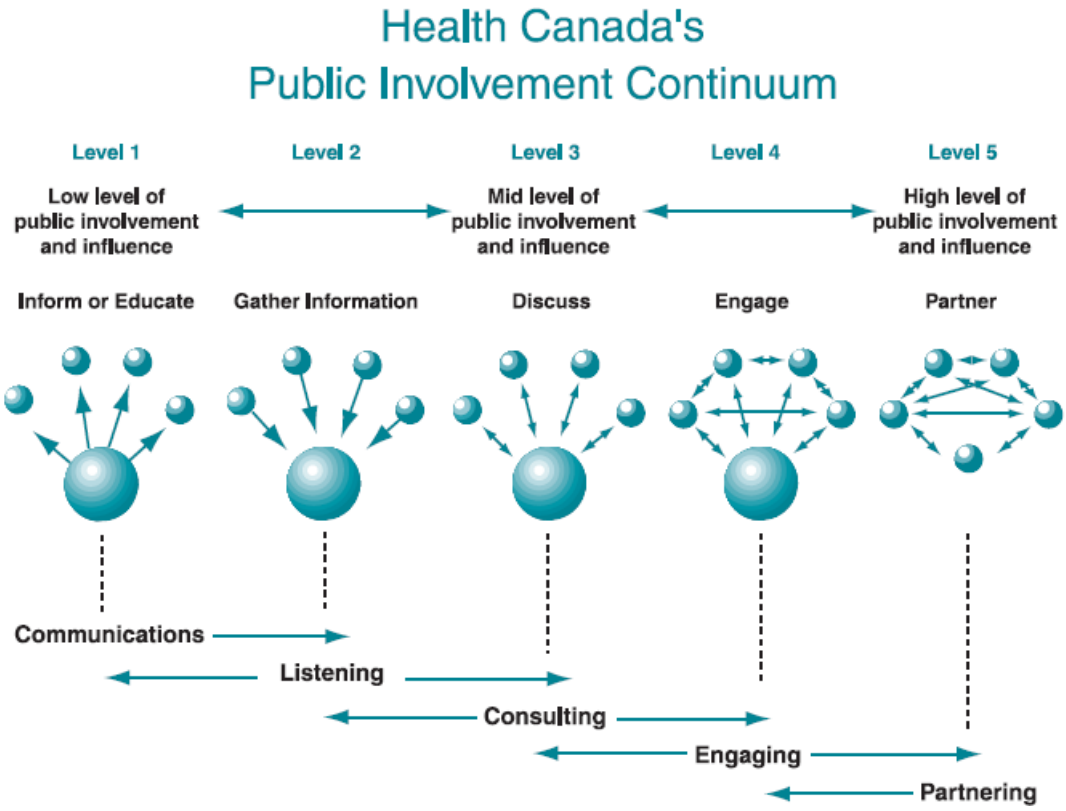
The framework also provides this model of 'types of consumer involvement'. The framework additionally uses a similar 'levels of participation model', comparable to Arnstein, but examines organisational capacity and 'consumer capability'




CONSUMER CAPABILITY
ORGANISATIONAL CAPACITY
Steer clear objectives
Drive the organisation towards achieving objectives
Commits an organisational objective to consumers/ consumer organisations and acts on outcomes
Involves consumers in setting policy and strategic directions
Set priorities, lead major activities
CONSUMER-LED
Credible knowledge and experience
Shared responsibility
Produce mutual objectives
Engages consumer organisations in partnerships
Consumers fully integrated in boards, working parties and all aspects of the organisations, including best practice improvements
Work equally with health professionals, administrators, researchers, policy makers
PARTNERSHIP
Access learning and development
Understand the objectives
Mentoring
Represent the broad view
Strategic thinking
Provide education and training
Selection
Facilitation
Building consumer involvement into all aspects of the organisation
Networking opportunities
Involved in information, support, cancer services, policy, research and spanning the patient pathway
INVOLVING
Understand the context
Experience of disease
Motivation
Communication
Consult focus groups surveys
Consultative workshops
Seek information, provide feedback
CONSULTING
Health literacy
Feedback/forums
Newsletters/resources (oral, electronic, print, web)
Provide information, seek feedback, build awareness, improve health literacy
INFORMING
LEVELS OF PARTICIPATION
LEVELS OF PARTICIPATION
LEVELS OF PARTICIPATION

Health Canada

Health Canada developed a model for public involvement based on a continuum of five levels of public involvement; from low level involvement to high level involvement[99]:



The model outlines the following levels

Level 1 Inform/educate when:

- factual information is needed to describe a policy, program or process
- a decision has already been made (no decision is required)
- the public needs to know the results of a process
- there is no opportunity to influence the final outcome
- there is need for acceptance of a proposal or decision before a decision may be made
- an emergency or crisis requires immediate action
- information is necessary to abate concerns or prepare for involvement
- the issue is relatively simple

Level 2 Gather information/views when:

- the purpose is primarily to listen and gather information
- policy decisions are still being shaped and discretion is required
- there may not be a firm commitment to do anything with the views collected (we advise participants from the outset of this intention to manage expectations)

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99 http://www.hc-sc.gc.ca/ahc-asc/alt_formats/pacrb-dgapcr/pdf/public-consult/2000decision-eng.pdf

Level 3 Discuss or involve when:

- we need two-way information exchange
- individuals and groups have an interest in the issue and will likely be affected by the outcome
- there is an opportunity to influence the final outcome
- we wish to encourage discussion among and with stakeholders
- input may shape policy directions/program delivery

Level 4 Engage when:

- we need citizens to talk to each other regarding complex, value-laden issues
- there is a capacity for citizens to shape policies and decisions that affect them
- there is opportunity for shared agenda setting and open time frames for deliberation on issues
- options generated together will be respected

Level 5 Partner when:

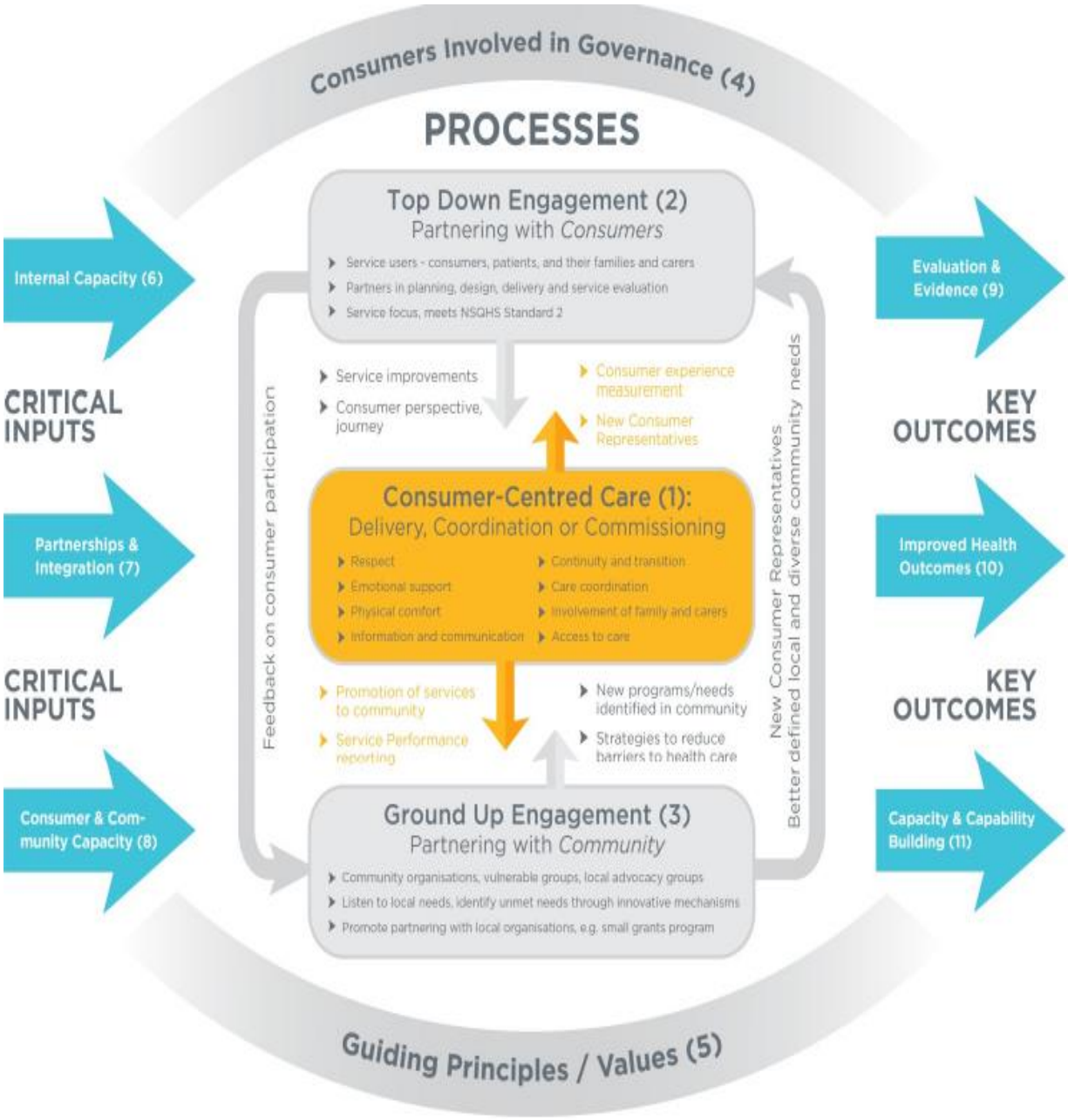
- we want to empower citizens and groups to manage the process
- citizens and groups have accepted the challenge of developing solutions themselves
- we are ready to assume the role of enabler
- there is an agreement to implement solutions generated by citizens and groups

To summarize, the decision to inform, consult or engage and the related selection of a public involvement strategy is dependent on a number of complex, interrelated factors:

- tailoring of approaches for involvement with goal and phase of policy making
- level of influence and involvement participants expect to have
- nature and complexity of issues
- participant profiles (e.g. mix of citizen vs. group representatives)
- previous experience of organizers with various techniques
- level of concern and media attention around the issues
- timelines
- financial costs
- human Resources and expertise
- degree of federal/provincial/territorial collaboration required
- level of support from stakeholders/partners
- level of political support in department or across government. (Health Canada 2000, p.12 - 14)

Health Consumers NSW

In 2015, Wentwest and Health Consumers NSW developed a Consumer and Community Engagement Model to identify how to improve consumer-centred care in the primary care[100]. The model incorporates a 'top down' and 'ground up' approach. The model outlines how consumers are involved in governance; describes the guiding principles and values of public involvement; and the critical inputs and key outcomes of the engagement process.



100 http://web.archive.org/web/20151120051152/http://www.hcnsw.org.au/data/Resources/2015_07_17_Final_report_and_template.pdf

Health Issues Centre

The Health Issues Centre developed a model for consumer engagement for the Southern Melbourne Integrated Cancer Services (Victoria)[101]. This model was for consumer engagement in quality improvement.

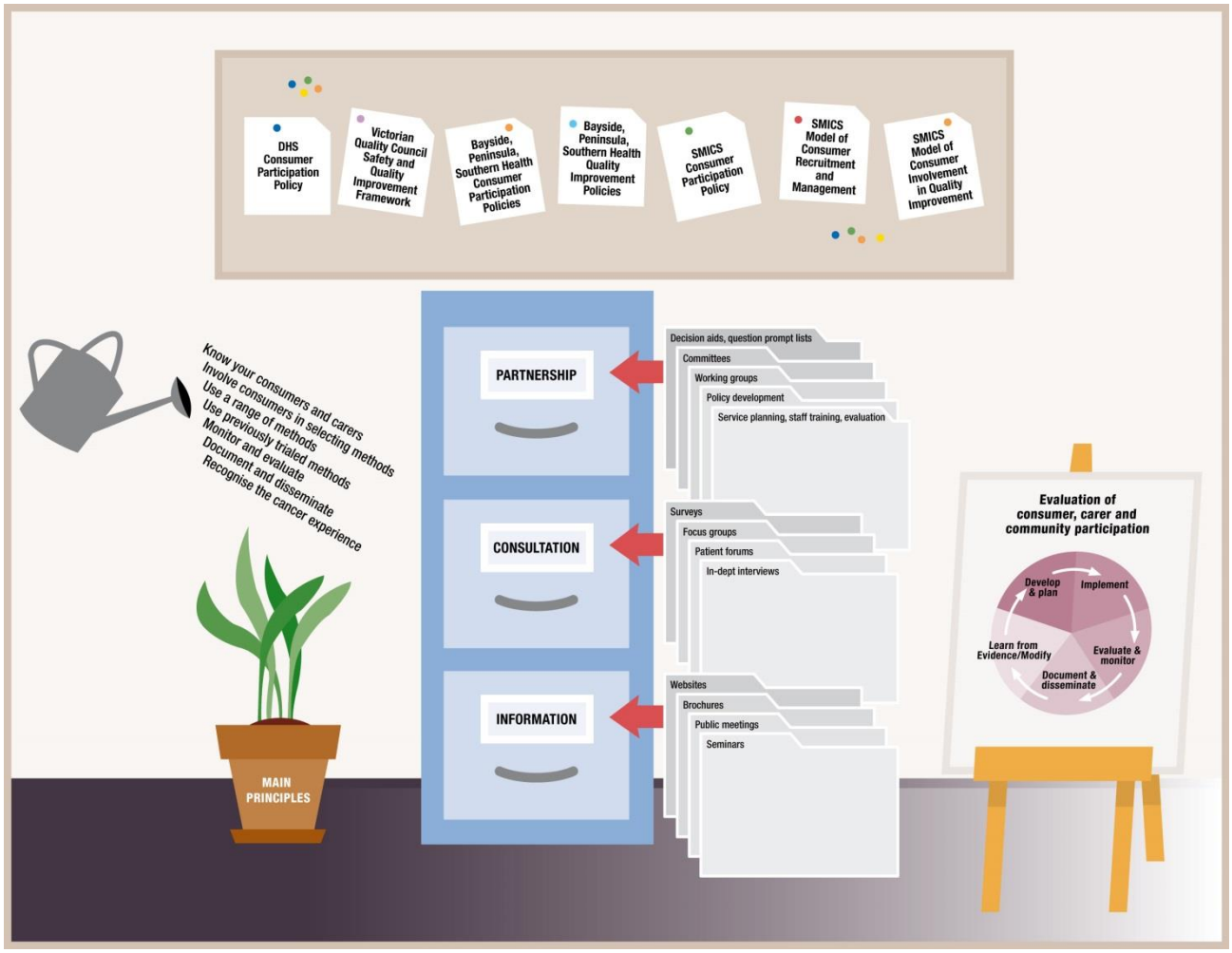
The 'pin-board' represents the policies and frameworks that inform the planning and implementation of consumer participation.

The 'pot plant and watering can' represent the main principles that are required to guide planning and implementation.

The 'filing cabinet' consists of three drawers titled partnership, consultation and information. These drawers signify three approaches to consumer participation and their contents include a variety of methods that can be used for participation.

The 'easel' suggests that the whole process of planning and implementing consumer participation needs to include an ongoing evaluating and monitoring process.

101 http://web.archive.org/web/20151126042923/http://www.healthissuescentre.org.au/images/uploads/resources/Consumer-participation-resource-for-researchers.pdf


DHS Consumer Participation Policy
Victorian Quality Council Safety and Quality Improvement Framework
Bayside, Peninsula, Southern Health Consumer Participation Policies
Bayside, Peninsula, Southern Health Quality Improvement Policies
SMICS Consumer Participation Policy
SMICS Model of Consumer Recruitment and Management
SMICS Model of Consumer Involvement in Quality Improvement
Know your consumers and carers
Involve consumers in selecting methods
Use a range of methods
Use previously trialed methods
Monitor and evaluate
Document and disseminate
Recognise the cancer experience
MAIN PRINCIPLES
PARTNERSHIP
CONSULTATION
INFORMATION
Decision aids, question prompt lists
Committees
Working groups
Policy development
Service planning, staff training, evaluation
Surveys
Focus groups
Patient forums
In-dept interviews
Websites
Brochures
Public meetings
Seminars
Evaluation of consumer, carer and community participation
Develop & plan
Implement
Evaluate & monitor
Document & disseminate
Learn from Evidence/Modify

Significant themes

This section identifies significant themes which were identified during the literature review.

The themes identified were:

- Social and ethical issues
- Public Involvement
- Learning, training, education and development

Summary of documents relevant to significant themes

While many documents agree and overlap, the following table summarises which documents in particular explored significant themes identified in the review.

Theme	REF	Link	Issuing Entity	Title
Social and ethical issues	A018	https://drive.google.com/open?id=0BwQTUgazNAy5RkxwVXVZRlRKSUE	Social Sciences & Medicine	Eliciting ethical and social values in health technology assessment: A participatory approach
	A024	https://drive.google.com/open?id=0BwQTUgazNAy5YWRiZ2JMNDZBRTA	International Journal of Technology Assessment in Health Care	Socio-ethical issues in personalized medicine: a systematic review of English language health technology assessments of gene expression profiling tests for breast cancer prognosis
Policy, decision	A001	https://drive.google.com/open?id=0	Health Policy 82	Bringing 'the public' into health technology assessment and coverage policy decisions: From principles to practice

making		ByyGFVQF01AMNXZQMXZDQkhlM1U		
	A002	http://web.archive.org/web/20151106063004/http://www.biomedcentral.com/content/pdf/s12911-015-0176-0.pdf	BMC Medical Informatics and Decision Making	Public preferences for engagement in Health Technology Assessment decision-making: protocol of a mixed methods study
Public involvement	A005	https://drive.google.com/open?id=0BwQTUgazNAy5ZTB1ZzVCcm9Cb2s	International Journal of Technology Assessment in Health Care	Perspectives on health technology assessment: response from the patient's perspective
	A007	https://drive.google.com/open?id=0BwQTUgazNAy5V2FwbDh6MTlsZGc	Health Policy 69	A consumer involvement model for health technology assessment in Canada
	A010	https://drive.google.com/open?id=0BwQTUgazNAy5c0R6a3l1Y19acmc	BMC Health Service Research	Study Protocol: Introducing patient perspective in health technology assessment at the local level
	A012	https://drive.google.com/open?id=0BwQTUgazNAy5LUMxM09pVXRiQkU	International Journal of Technology Assessment in Health Care	Survey on the involvement of consumers in health technology assessment programs
	A014	https://drive.goog	BMC Health Service	Involving patients in HTA activities at local level: a study protocol based on the

		le.com/open?id=0BwQTUgazNAy5enJkSllGN2ZrRVU	Research	collaboration between researchers and knowledge users
	A015	https://drive.google.com/open?id=0BwQTUgazNAy5b3huQ2JWS1pwTm8	BMC Health Service Research	Involving patient in the early stages of health technology assessment (HTA): a study protocol
	A016	https://drive.google.com/open?id=0BwQTUgazNAy5VXhDTUtQZE8zcWM	Social Sciences & Medicine	"It all depends": Conceptualizing public involvement in the context of health technology assessment agencies
	A017	https://drive.google.com/open?id=0BwQTUgazNAy5c1RVLVVERjZnbGs	International Journal of Technology Assessment in Health Care	Consumer involvement in the health technology assessment program
	A022	https://drive.google.com/open?id=0BwQTUgazNAy5WEZNN2lvejlOQkU	Patient	A Pilot Study to Identify Areas for Further Improvements in Patient and Public Involvement in Health Technology Assessments for Medicines
	A025	https://drive.google.com/open?id=0BwQTUgazNAy5ZklvWjFKdlpNdWM	International Journal of Technology Assessment in Health Care	Health technology assessment use and dissemination by patient and consumer groups: Why and how?
	A028	https://drive.google.com/open?id=0	International Journal of	Does the public think it is reasonable to wait for more evidence before funding innovative health technologies? The case of PET scanning in Ontario

		BwQTUgazNAy5RnIxQlJ6UFFIMW8	Technology Assessment in Health Care	
	A029	https://drive.google.com/open?id=0BwQTUgazNAy5bjZleHJkS2xiUkE	BMJ Publishing Group	Public involvement in research should be “second nature” by 2025, review concludes
	A037	https://drive.google.com/open?id=0BwQTUgazNAy5UEROckEwbl96VEE	Expert Reviews Ltd	Role of patient and public participation in health technology assessment and coverage decisions
	A038	https://drive.google.com/open?id=0BwQTUgazNAy5emxzTl9OME9Wd1k	International Journal of Technology Assessment in Health Care	Involvement of consumers in health technology assessment activities by INAHTA agencies
Learning, training, education and development	A004	https://drive.google.com/open?id=0BwQTUgazNAy5NW9tZGpYVmN3bHM	European Heart Journal	Health technology assessment in interventional electrophysiology and device therapy: a position paper of the European Heart Rhythm Association†
	A007	https://drive.google.com/open?id=0BwQTUgazNAy5V2FwbDh6MTlsZGc	Health Policy 69	A consumer involvement model for health technology assessment in Canada
	A016	https://drive.google.com/open?id=0BwQTUgazNAy5VXhDTUtQZE8zcW	Social Sciences & Medicine	“It all depends”: Conceptualizing public involvement in the context of health technology assessment agencies

		M		
	A017	https://drive.google.com/open?id=0BwQTUgazNAy5c1RVLVVERjZnbGs	International Journal of Technology Assessment in Health Care	Consumer involvement in the health technology assessment program
	A022	https://drive.google.com/open?id=0BwQTUgazNAy5WEZNN2lvejlOQkU	Patient	A Pilot Study to Identify Areas for Further Improvements in Patient and Public Involvement in Health Technology Assessments for Medicines
	A015	https://drive.google.com/open?id=0BwQTUgazNAy5b3huQ2JWS1pwTm8	BMC Health Service Research	Involving patient in the early stages of health technology assessment (HTA): a study protocol
	A033	https://drive.google.com/open?id=0BwQTUgazNAy5SXUyMUsydFN4VE0	Consumer Health Forum of Australia	Consumer Participation in the Review of Health Technology Assessment Report on outcomes of consumer consultations
	A036	https://drive.google.com/open?id=0BwQTUgazNAy5b3BjNEQ4V2N2VHM	Journal of Health Politics, Policy and Law	Public Engagement in Health Technology Assessment and Coverage Decisions: A Study of Experiences in France, Germany, and the United Kingdom
	A037	https://drive.google.com/open?id=0BwQTUgazNAy5UERObkEwbl96VEE	Expert Reviews Ltd	Role of patient and public participation in health technology assessment and coverage decisions

Key learning points from significant themes

This section attempts to articulate key learning points from the literature review, in order to help inform decision making about best-next steps. It is organised according to the significant themes explored in the previous section.

Social and ethical issues

The public interest

Natural balances need to exist between Government, acting in the public interest and 'politically accountable for their resource allocation decisions' (Abelson, A001)[102], and industry, often acting in the interest of private investors. Public involvement 'increases transparency' (Wortley, A002)[103].

A key question that arose in the review was regarding pricing. Aside from 'differential pricing between industrialised and developing countries', members of the public ask if drugs are priced at what they cost to produce, or what the market is willing to pay (Trouiller, A050)[104].

> 'Engagement with an industry whose strategy has so far largely been to maximise profit in the West, rather than establish an equitable pricing policy worldwide, requires careful management of intellectual property'

The ethical and moral debates around this rely on transparency on both sides. An organisation attempting to bridge this gap is the European Patients' Academy, which aims to:

> 'help patients be more educated and involved in the research and development process of new medicines by offering reliable, objective, comprehensive lay-friendly information and training on the research and development process of medicines. We will increase the capacity of patients to be effective advocates with meaningful involvement in areas like drug discovery and non-clinical testing, planning and conduct of clinical trials, regulatory affairs, assessment of safety of medicines, benefit-risk assessment, as well as principles of health technology assessment.'[105]

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[102] https://drive.google.com/file/d/0ByyGFVQF01AMNXZQMXZDQkhlM1U/view

[103] http://web.archive.org/web/20151106063004/http://www.biomedcentral.com/content/pdf/s12911-015-0176-0.pdf

[104] http://web.archive.org/web/20151117102634/http://fieldresearch.msf.org/msf/bitstream/10144/28441/1/Access%20Trouiller%202002.pdf

[105] http://web.archive.org/save/http://www.patientsacademy.eu/index.php/en/about-eupati/8-patients-academy-a-new-way

The MBS Review Consultation Paper states that 'the Review is clinician led' in order to 'minimise real and perceived conflicts of interest'[106], yet lacks any independent review, comparable to the NICE Citizens Council.

The same report makes reference to the 'Choosing Wisely' model, which is:

> 'founded on the principles of managing conflicts of interest, improving the quality of care, improving access to care, and promoting the just distribution of finite resources. It brings together clinicians and consumers and considers services which are of questionable value, to inform the decisions of clinicians and to empower consumers to participate in conversations with their doctor about their care'[107]

The Choosing Wisely campaign will be 'facilitated' and evaluated in Australia by NPS MedicineWise[108] (known prior to 2009 as the National Prescribing Service[109]), who 'work with health professionals, consumers, government and industry to improve the health of all Australians through the quality use of medicines and medical tests'. It is interesting to note that they state 'We also work extensively with consumers,' without giving any detail or clear ways for people to get involved.

The 'bringing together' of the public (or representatives) with subject experts in a transparent way is key to maintaining trust in the appraisal process. The report by the NICE Citizens Council states that the transparency of such processes can affect 'perceptions that values such as justice, equality and trust are not being upheld'[110].

Public involvement

Failure of evidence-based medicine to involve the public

Fundamental biases in evidence-based medicine (and thus any organisation informed by this evidence) are proposed in the paper 'Six 'biases' against patients and carers in evidence-based medicine' (Greenhalgh, A048)[111]. The authors state:

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106 http://web.archive.org/web/20151120124310/http://www.health.gov.au/internet/main/publishing.nsf/Content/922CB2933B0F1645CA257EC1001D5C12/$File/MBS%20Review_Consultation%20paper_FINAL.pdf

107 http://web.archive.org/web/20151120124310/http://www.health.gov.au/internet/main/publishing.nsf/Content/922CB2933B0F1645CA257EC1001D5C12/$File/MBS%20Review_Consultation%20paper_FINAL.pdf

108 http://web.archive.org/web/20151127011217/http://www.nps.org.au/media-centre/media-releases/repository/choosing-wisely-australia-launching-in-2015

109 https://en.wikipedia.org/wiki/NPS_MedicineWise

110 http://web.archive.org/web/20151120091727/http://www.nice.org.uk/Media/Default/Get-involved/Citizens-Council/Reports/cc-report17-equity-efficiency.pdf

111 http://web.archive.org/web/20151117045807/http://www.biomedcentral.com/content/pdf/s12916-015-0437-x.pdf

> 'Evidence-based medicine (EBM) is maturing from its early focus on epidemiology to embrace a wider range of disciplines and methodologies. At the heart of EBM is the patient, whose informed choices have long been recognised as paramount. However, good evidence-based care is more than choices. We discuss six potential 'biases' in EBM that may inadvertently devalue the patient and carer agenda. To reduce these 'biases', EBM should embrace patient involvement in research, make more systematic use of individual ('personally significant') evidence, take a more interdisciplinary and humanistic view of consultations, address unequal power dynamics in healthcare encounters, support patient communities, and address the inverse care law.'

The six biases they identify are:

- limited patient input to research design,
- low status given to experience in the hierarchy of evidence,
- a tendency to conflate patient-centred consulting with use of decision tools;
- insufficient attention to power imbalances that suppress the patient's voice,
- over-emphasis on the clinical consultation,
- a focus on people who seek and obtain care (rather than the hidden denominator of those that do not seek or cannot access care).

In addition to this, Messina also states that 'the exact point to seek input from patients and the public is controversial; however, it suggests that 'those involved within HTAs agree that patients/the public are usually involved too late in the process' (Messina, A022)[112]. Messina adds:

> Involving patients from the start, in trial design, can greatly impact on the relevance of the final product and the associated 'evidence.'

[112] Involving patients from the start, in trial design, can greatly impact on the relevance of the final product and the associated 'evidence.'[

Social determinants of involvement

While the social determinants of health have been clearly defined by World Health Organisation[113], the social determinants of involvement are equally important to consider when involving the public.

Accepting that you can't involve everyone in everything it is therefore important to consider how you can include as many people as possible within your resources. This includes considering who you might be unconsciously excluding through certain kinds of involvement (for example, face to face meetings might not be possible for some to attend) so it is important to consider how you can reduce barriers to involvement.

The NICE report (explored in the section of this report 'Significant reports by the Citizens Council') extensively explores 'tensions between equity and efficiency?'[114].

Whatever the 'tension' and 'trade off', it is important that the public are involved in deciding where compromises are made and that the decision making process is transparent, so as to avoid perceptions of deliberate or unconscious exclusion of certain people.

It is also important to acknowledge what can be thought of as the 'screaming silences' from people who may be unintentionally marginalised[115].

The two following resources have been adapted to support members of the Medicare Benefits Schedule Review Taskforce appraise their plans for involvement.

The resource on the next page, adapted from a resource produced by Jack Nunn for Macmillan Cancer Support, summarises ways of identifying ways people may be excluded from involvement and overcoming certain barriers to involvement[116].

'Supporting public involvement' was created by Jack Nunn for Macmillan Cancer Support and has been adapted for this report.

What are you doing? Was created by Jack Nunn for the Health Issues Centre and has been adapted for this report, informed by the literature review.

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[113] http://www.who.int/social_determinants/en/

[114] http://web.archive.org/web/20151120091727/http://www.nice.org.uk/Media/Default/Get-involved/Citizens-Council/Reports/cc-report17-equity-efficiency.pdf

[115] http://web.archive.org/web/20151126060635/http://jrn.sagepub.com/content/early/2010/11/11/1744987110387741

[116] http://learnzone.org.uk/courses/course.php?id=228

Supporting public involvement

There are many things to think about when involving the public and patients in improving the Medicare Benefits Schedule – this document is intended to help ask the right questions for the right roles.

How to use this resource: Under 'Assumptions and barriers', read the questions and consider if these might be barriers to involving some people, and consider how you might overcome these. 'Learning needs and support' examines the role in more detail and asks questions about the support people might need to develop.

Assumptions and barriers	Role Description	Learning needs & support
• What commitment do you expect (time/financial implications) • Have you asked people to think about their emotional readiness? • Do you expect them to be reading and writing information and documents? Have you considered what formats might be appropriate? • Are you assuming a good ability to speak and read English? • Do you expect a certain educational background?	**Lay Leader:** A person who speaks and acts on behalf of all members of the public, including patients and carers and who takes a leading role in representing other lay representatives. The role may involve holding people or organisations to account	**How are they a representative?** • How will they be gathering views? • Will this involve research? • Do they have a budget? • Should they be paid? • Is there admin and practical support (from an organisation?) • Is there any training available? **Who is already doing this?** • Are there any opportunities for them to be involved in peer support or have or be a buddy? • What can be shared with other organisations? (E.g. learning, resources) **How are people involved?** • Is it face to face meetings? • Can people be involved in other ways? • What can be done online, what cannot?
	Lay representative: a member of the public (not a professional) who is a representative. They must speak and act on behalf of others. They may be guided by lay leaders but will be expected to take direct action to ensure that they are informed and able to represent the views of others.	
• Are the people who have engaged with you the only people who might be interested?	**Interested and engaged members of the public:** People who know about and/or are interested in decisions being made, but may take no direct action other than giving feedback or signing petitions	**Could there be a need for translation?** • Are there any groups or organisations who could support with this?
	Uninformed, disengaged or disinterested members of the public: people who, for whatever reason, are not engaged, informed or interested in influencing decision making or shaping the future of health and social services.	**A majority of the population are in this category.** • What information or support might some people need to help them move into other roles? • What might make people move back into this role? (e.g. not seeing direct improvements, or

too much of organisational change?

What are you doing?

There are many ways to involve people in the work of the Medicare Benefits Schedule Review.

How to use this resource: The left hand column shows the kinds of actions you can take, the right hand column gives ideas for how people can be involved in these actions. The width of the pyramid is a guide to the number of people likely to be involved

Actions		Involve people by:
Innovating This includes prototyping, piloting, establishing and creating new ways of doing things. This can include anything from building partnerships or doing research.		**Supporting them to:** • Design and carry out research • Create solutions • Implement ideas • Learn from actions
Managing, delivering and evaluating Working in partnership to manage ongoing activities.		**Having:** • Clear roles for the public • Elections and interviews when appropriate • Clear and accessible accountabilities for all roles (including staff), groups and committees. **Asking them to take actions such as:** • Managing or overseeing actions and processes • Directly delivering services or reviewing providers • Evaluating actions, processes and outcomes
Prioritising and planning Working in partnership to prioritise actions and plan implementation.	**Proactive**	• Agreeing priorities in a clear, transparent way* • Having clear accountabilities for planning at all stages • Having a transparent and adaptable budget *(this can include stopping certain actions)
Listening, responding and acting Actively seeking feedback, responding to ideas, compliments and complaints with actions.	**Reactive**	**Asking them to help:** • Interpret feedback • Influence responses to ideas, compliments and complaints • Asking for ideas for actions **Remember to always take action**, however big or small. This includes telling people what this action was, particularly those who have given feedback.
Asking and discussing Asking people what they think, need and want and discussing it with them.		Inviting people from your intended audience or people you are trying to help to: • Design **how** you will collect feedback and **interpret** the results • Identify any potential barriers that might stop people from giving feedback.
Telling Giving information about what you have done, are doing or are going to do.		• Sharing opportunities to be involved • Asking people for ideas and support to share and disseminate what you want to tell people

Before involving people, always ask:
- Could this be more accessible? (is it online? Does it use appropriate language – tone and tongue?)
- Is there any way I could support involvement? (learning and development, financial support?)

Please note the term 'people' includes the general public, patients, consumers, carers and service users.
An 'action' is anything people are doing, individually or on behalf of an organisation.

* This is the 'leading edge'.

Created by Jack Nunn with the Health Issues Centre

Creating opportunities for learning, education, training and development

Key quotations

From 'A Pilot Study to Identify Areas for Further Improvements in Patient and Public Involvement in Health Technology Assessments for Medicines', Messina[117]

- Education of patient groups and committees was essential in the creation of active and informed agents in medicine HTAs.
- More research, funding, education, and HTA process changes are required to shift patients and the public towards the center of the decision-making model.
- Education and using innovative methods of reaching patients, as well as adequate mechanisms for feedback in the process, were noted as suitable options for enhancing consultation in HTAs.

From 'Consumer Participation in the Review of Health Technology Assessment Report on outcomes of consumer consultations', Consumer Health Forum [118]

- Consumers suggested that consumer education should be an integral function of the new HTA system.
- Consumer education is insufficient, and that there should also be education of health professionals. Health literacy programs could enable them to communicate better with health consumers about health technologies. This would improve consumers'' ability to provide informed consent when their health professionals are proposing the use of a technology in their treatment.

[117] https://drive.google.com/open?id=0BwQTUgazNAy5WEZNN2lvejlOQkU

118 https://drive.google.com/open?id=0BwQTUgazNAy5SXUyMUsydFN4VE0

Quotations relevant to learning, education, training and development

REF	Link	Issuing Entity	Title	Quotations relevant to learning, education, training and development
A004	https://drive.google.com/open?id=0BwQTUgazNAy5NW9tZGpYVmN3bHM	European Heart Journal	Health technology assessment in interventional electrophysiology and device therapy: a position paper of the European Heart Rhythm Association†	Issues related to training, education, definition of the appropriate setting for therapy delivery need to be considered and addressed.
A016	https://drive.google.com/open?id=0BwQTUgazNAy5VXhDTUtQZE8zcWM	Social Sciences & Medicine	"It all depends": Conceptualizing public involvement in the context of health technology assessment agencies	Public education about HTA "in the interest of allaying some of the anxiety commonly expressed by lay people [and to educate] the mass of the people on medical matters, an important area of civilised discourse"
A017	https://drive.google.com/open?id=0BwQTUgazNAy5c1RVLVVERjZnbGs	International Journal of Technology Assessment in Health Care	Consumer involvement in the health technology assessment program	Training and procedures were developed for staff 'to enable them to take on the role of identifying and contacting consumers to comment' Training for fellow panel members, especially chairmen, is valuable.
A022	https://dr	Patient	A Pilot Study to Identify	Involvement of patients and the public is superior to consultative methods, and that

	ive.google.com/open?id=0BwQTUgazNAy5WEZNN2lvejl0QkU	Areas for Further Improvements in Patient and Public Involvement in Health Technology Assessments for Medicines	patients and the public can join the decision- making table. This requires a nurturing climate for participation along with adequate support during the process and appropriate education and training. NICE, a recognized leader in patient and public involvement in HTA, has undertaken work to evaluate the success of its program, which reveals that it is making a positive impact, but training and education were identified as an area for improvement. Education will help patient and public advocates develop appropriate skills to participate in HTA debates and may also assist in providing professionals with the skills to understand and make use of patients' experiences and views. Education programs are already underway in Canada and the UK (for example, the London School of Economics Summer School) and are under discussion in Australia but in- creased funding would ensure these programs are a priority. HTA agencies should be responsible for funding public and patient involvement initiatives. Additional phases of research are also planned in the area of how to better prepare patient groups to be part of the HTA process through ongoing training and development. Education and using innovative methods of reaching patients, as well as adequate mechanisms for feedback in the process, were noted as suitable options for enhancing consultation in HTAs. There was a strong theme of education of patients and the public so that they can be an active part of HTAs. Education of patient groups and committees was essential in the creation of active and informed agents in medicine HTAs. Australia, Canada, and the UK are rising to the challenge [of public involvement]; much can be learned from the efforts of agencies in these three countries. However, more research, funding, education, and HTA process changes are required to shift patients and the public towards the center of the decision-making model. An educated public can provide quality information on citizen's values, needs, judgments, prioritization and technology preferences.

A015	https://drive.google.com/open?id=0BwQTUgazNAy5b3huQ2JWS1pwTm8	BMC Health Service Research	Involving patient in the early stages of health technology assessment (HTA): a study protocol	The evaluation of public involvement in HTA prioritization in the UK has demonstrated the importance of providing dedicated staff and regular feedback to support this involvement. Therefore, patients will receive training in HTA and evidence-informed healthcare before the prioritization meeting. A member of the research team will also provide ongoing support for patient representatives throughout the process.
A033	https://drive.google.com/open?id=0BwQTUgazNAy5SXUyMUsydFN4VE0	Consumer Health Forum of Australia	Consumer Participation in the Review of Health Technology Assessment Report on outcomes of consumer consultations	Key recommendations of the Consumer Health Forum report were: Extensive consumer education to ensure consumers understand medical devices and technologies and the system designed to regulate their use Consumer education programs should be developed to ensure that consumers have a strong understanding of both medical devices and technologies and the HTA system designed to regulate their use in Australia. Consumers suggested that consumer education should be an integral function of the new HTA system Consumers strongly endorsed widespread consumer education on health technologies and the HTA process, so that consumers: Know about the elements of the HTA system, including compliance requirements, Understand the benefits and risks of using (or not using) various devices - ensuring complaints mechanisms, and where to report adverse events - enabling consumers to feed into the HTA system and ensuring learnings from current patient experiences (about what works and what does not) and the patient‟s journey are taken into account in the assessment and review processes. Long-term education should begin in schools, and emphasise the rights of all health consumers. Consumer education is insufficient, and that there should also be education of health professionals. Health literacy programs could enable them to communicate better with health consumers about health technologies. This would improve consumers‟ ability to provide informed consent when their health professionals are proposing the use of a

				technology in their treatment. Consumers indicated the need for education about adverse incident reporting to support shared decision making on the use of health technologies.
A037	https://drive.google.com/open?id=0BwQTUgazNAy5UEROckEwbl96VEE	Expert Reviews Ltd	Role of patient and public participation in health technology assessment and coverage decisions	Training of patient or public representatives on committees: to ensure that patient or public representatives feel able to contribute meaningfully to discussions, there is a need for educational opportunities that introduce them to basic terms, concepts and policy options;
NA	http://web.archive.org/web/20150304054755/http://www.nice.org.uk/about/nice-communities/public-involvement/patient-and-public-involvement-policy	Website	Patient and public involvement policy	NICE 'offer support and training to lay people who contribute to NICE's work'

A checklist of questions to ask at the start of public involvement in HTA

This short list of questions has been collated from knowledge gained from the literature review and was written by Jack Nunn and Jo Root. The questions are designed to stimulate the creation of a robust and transparent model of public involvement in the HTA process.

Why do the public need to be involved?

- Are there any exclusions, are there certain people you don't want to involve? Why?
- Are there any people who might need additional support to be involved? What support might they need?

What stage of your process are you planning to involve the public?

- Are you planning to involve them from the start? If not, why?
- Will you involve the public in helping you plan how you will involve the public?
- Do you want different people involved at different stages? Why?

How will you involve the public?

- Have you involved the public in planning how you will involve the public? For example, have you asked members of the public if they think your plans may unintentionally exclude some people?
- Have you got adequate resources or is there a limit to your involvement capacity? Have you been transparent about this limit?

How will you let people know what you are doing?

- Will the public be involved in helping you plan how you will let people know how to be involved (for example, recruitment or dissemination)

How will you evaluate your public involvement?

- Have you planned adequate resources to evaluate involvement, including a longer term impact assessment?
- Will you publish or share the results of your evaluation so other may share in any learning.

Appendix

Search report

Method

Search strategies included searching:

- Peer reviewed journals (including using MEDLINE and library search engines)
- Grey literature (including Government papers, NGO literature, academic literature, relevant websites) using search engines such as 'Google'
- Social media (a search of social media for key terms, including blogs)

In addition, a number of interviews were conducted with international subject experts.

Owing to time and language-constraints, the search only included English language searches.

The three main categories of the search were (please note '/' denotes the 'OR' boolean operator):

- Health technology AND patient/consumer/public/community/citizen involvement/participation/engagement
- Health technology assessment AND patient/consumer/public/community/user/citizen AND involvement/participation/engagement
- Models/framework AND patient/consumer/public/community/user/citizen AND involvement/participation/engagement

Please note that in the 'Full data extraction output', a record was kept of how each individual document was found, and where those search terms were entered.

Summary of search

Search terms	Database/ Website URL	Documents searched (number)	Documents REF (list all docs in this search)
Health technology assessment	Latrobe search engine	18	A001, A010, A016,A017, A018, A019, A020, A021, A022, A023, A024, A025, A026, A027, A028, A029, A030, A003
Health device	Latrobe search engine	5	A004, A012, A013, A014, A015
Health technology assessment, subcategory 'patient participation'	MEDLINE	1	A005
Health technology assessment	MEDLINE	3	A006, A008, A011
Consumer involvement in health technology	Latrobe search engine	1	A007
Health technology assessment subcategory 'organisations & Administration'	MEDLINE	1	A009
health technology assessment	Google	5	A031, A032, A022, A034, A035, A041
Public engagement in health technology assessments	Latrobe search engine	1	A002
Interview with experts		4	A036, A037, A038, A039
Health Technology Assessment AND development AND training	CINAHL	2	A044, A045
Health technology assessment government	Google	1	A041

Exclusion criteria

As this project involved a 'rapid literature review', rather than, for example, a 'systematic review' a number of decisions were made in order to balance efficiency and effectiveness.

Regarding inclusion and exclusion criteria, a number were proposed before the search began, but owing to the paucity of literature, the results suggested a simple date range exclusion would be the most effective. As a result, anything before the year 2000 was excluded, as this date represented the time period that relevant literature began to emerge.

Some documents were deemed 'out of scope' and not relevant. Records were kept of which documents were excluded and why.

Documents published by MBS were not included in the search but are referenced in the report where appropriate.

Please note, this search only included English language documents.

Exclusions were:

- Must be after 2000
- Must be in English

Appraisal of the literature review and report

The following points are a short appraisal of the process of creating this literature review and report:

Limited time:

- As this project involved a 'rapid literature review', rather than, for example, a 'systematic review' a number of decisions were made in order to balance efficiency and effectiveness.
- The literature search and data extraction was completed in 49 hours (this does not include the time taken to synthesise data and the creation of this report).
- Exclusion criteria were applied retrospectively, based on the findings.

Possible publication bias:

- The literature review returned a limited amount of literature on the subject, in relation to what might be expected considering the number of organisations involved in this work. This suggests there may be an inherent publication bias, or other factors influencing the paucity of literature on this subject. Further research would be required to answer this question.

Lack of systematic evaluation:

- The literature search found no apparent validated methods for evaluating models of involving the public and the impact these might have, making it improper to report on any preferred methods.

Literature review - Data extraction output – Summary

This section contains a summary of the data extracted from the literature search. The full data extraction output can be accessed in the following ways:

Document type with link	Microsoft Excel	Comma-separated values (CSV)	Portable Document Format (PDF)	Google Doc

Please note 'REF' refers to the unique reference number assigned to each document during the literature search.

REF	Link	Issuing Entity	Title	Type / media	Year	Summary	Key learning points or recommendations
A001	https://drive.google.com/open?id=0ByyGFVQF01AMNXZQMXZDQkhlM1U	Health Policy 82	Bringing 'the public' into health technology assessment and coverage policy decisions: From principles to practice	Journal	2007	This paper offers a framework that clearly distinguishes specific roles for the public, and relates them to several layers of policy analysis and policy making where 'the public' may engage in different tasks. The framework offers a menu of choices for policy makers contemplating changes to public involvement, as well as a model that can be used to characterize	• There is a need for greater public involvement in HT and HTA's in Canada. • HTA and HT policy organizations face decisions about whether to approach public involvement in an ad-hoc or more institutionalized manner • Stakeholder involvement presented as public involvement gives greater voice to professionals and industry interests than to citizens and patients. Moreover, when "public" and "stakeholders" both sit at the table, inequalities in their powers of persuasion must be overcome if the public perspective is to have any force. • Discussion points: Public involvement models, choosing among models and mechanisms, who to involve, accountability, committee representation

						and analyze different approaches across jurisdictions.	"Governments are politically accountable for their resource allocation decisions Canadian policy makers are at an early stage in the design of legitimate mechanisms for the public to contribute to, and to be apprised of, HTA and coverage decisions As they consider the options, questions arise about whom to involve (e.g., which publics), how to engage them (e.g., through what public involvement or accountability mechanisms), and for what purpose (e.g., to inform the public of decisions and their rationales, or to have the public directly affect those decisions). The difference between public accountability and public participation, are not well articulated or distinguished in these debates."
A002	http://web.archive.org/web/20151106063004/http://www.biomed	BMC Medical Informatics and Decision Making	Public preferences for engagement in Health Technology Assessment decision-making: protocol of a mixed methods study	Journal	2015	This study will examine public preferences for engagement in Australian HTA decision-making using an exploratory mixed methods design. The objectives of this study are to determine if and how the public would like their views	• HTA organizations regularly make decisions about when and how public engagement should occur but without consideration of the public's preferences on the method and extent of engagement • Public engagement is a means to achieve these aims [of HTA], because it increases the transparency of the process and provides a mechanism to consider social values related to the technology being assessed • In HTA, public engagement methods can include basic information provision, to consultative

	central.com/content/pdf/s12911-015-0176-0.pdf					and preferences to be considered in HTAs and whether this differs depending upon the question posed by decision-makers and/or the characteristics of the HTA	mechanisms such as focus groups and consumer representation on decision making committees, to more complex methods of deliberation including citizens juries and consensus panels. • Understanding the effect of a decision involves issues such as the number of people with the condition, their characteristics (e.g. age, ethnicity), the perceived benefit of the technology (relative to the severity/burden of the condition), the availability of other treatment options, whether expert opinion is divided on the effectiveness of the technology and the cost of the technology • Internal decision-making context factors, on the other hand, are factors relating to the decision-making process. Such factors include the time and resources available to the HTAO, the organizational cultural of the HTAO. These factors are rarely made explicit in public engagement frameworks, but have been noted as being just as influential in determining when and how members of the public would be engaged. • None [of the studies analysed] have specifically considered the views of the general public • Policy makers [need to] to clarify what they want from the public in these circumstances [20] including the extent to which they are willing to cede or not, to the public's views.
A003	https://dri	BMC Health Service Research	Methods of international	Journal	2013	One component of HTAs are economic	There is a considerable unexplainable variance in recommendations. Further effort is needed to

	ve.google.com/open?id=0BwQTUgazNAy5dTlrNGJLYjBtQ3c		health technology assessment agencies for economic evaluations- a comparative analysis			aspects. To incorporate economic aspects commonly economic evaluations are performed. The objective of this paper is to provide an overview and comparison of the methodological recommendations of international HTA agencies for economic evaluations through comparative analysis research.	harmonize methods for preparing economic evaluations
A004	https://drive.google.com/open?id=0BwQTUgazNAy5NW9tZGpYVmN3bHM	European Heart Journal	Health technology assessment in interventional electrophysiology and device therapy: a position paper of the European Heart Rhythm Association†	Journal	2013	This position paper reviews a series of issues that are related to HTAs for catheter ablation and device therapy and that in our view deserve attention (economic evaluations, organisational and educational issues, sensitivity analyses).	THIS RECOMMENDATION RELAES TO CE IN HTA's: The scoping, assessment, and appraisal of an emerging therapy should address questions that are relevant to patient groups in which clinical effectiveness has been proved. As outlined in clinical practice guidelines, such patient groups should be defined in collaboration with experienced clinicians.
A005	https://dri	International Journal of	Perspectives on health	Journal	2004	This paper laments that those responsible	Engagement of patients and citizens ought to be encouraged at all stages in the HTA process, in

	ve.google.com/open?id=0BwQTUgazNAy5ZTB1ZzVCcm9Cb2s	Technology Assessment in Health Care	technology assessment: response from the patient's perspective			for HTA's should make greater efforts to involve the public and ensure that the findings of HTA's are accessible to patients for use when making treatment choices. Patients and the public make a valuable contribution to HTA's, yet the findings are not always accessible to them.	particular the following: • Determining priorities for assessment. • Designing and conducting assessments and appraisals • Receiving and using the findings from HTA. • Engaging in debates about policy priorities and rationing • Involving patients in the design of trials or reviews and choice of outcome measures can greatly increase the relevance of the final product • Involving patients in the design of trials or reviews and choice of outcome measures can greatly increase the relevance of the final product • What is needed is a systematic attempt to engage the views of citizens, to balance those of the specific interests. •Those responsible for health-care budgets must ensure that individual clinical decisions fit within the wider context of resource availability and public priorities. •Clinical freedom and patient choice cannot be divorced from its societal context, and when individual expectations clash with population priorities, there must be a mechanism for resolving the conflict interest groups
A006	https://drive.go	BMJ Publishing Group	NICE supports allowing	Letter	2014	Rebutal to the article by Wise claiming that "selling" scientific	Scientific advice is an essential tool for enabling constructive and structured dialogue between HTA decision making bodies and industry to ensure that

	ogle.com/open?id=0BwQTUgaznNAy5V2FwbDh6MTlsZGc		technology assessment bodies to provide advice to drug industry			advice procedures enables institutional capture by drug companies.	product development plans meet the requirements of decisions makers. In this way, scientific advice can facilitate the development of clinically effective, useful, and affordable medicines for the benefit of patients.
A007	https://drive.google.com/open?id=0BwQTUgaznNAy5V2FwbDh6MTlsZGc	Health Policy 69	A consumer involvement model for health technology assessment in Canada	Journal	2004	• Health consumers believe they should have a role in determining their treatment options. • By providing support and training, these organizations believe they would be capable of and are willing to devote a considerable amount of time and effort to have an influence on the assessment and evaluation of potential treatments and therapies and their availability for access.	• In order to have a fair and transparent process, an independent consumer led organization dedicated to health technology assessment should be created and supported by the national government. • This HTA consumer organization would be responsible for developing a network with health organizations, the development of a database of health consumers' expertise, knowledge, etc., the development of a formal health consumer stakeholder involvement process, the training and education of health consumers, information dissemination, and the evaluation of the processes and program. • These activities would provide this organization the support and resources needed to nominate the most effective health consumers to participate in HTA committees.

							• This model also requires the support of the central organization conducting HTA reviews to respect the health consumer stakeholder involvement process and provide resources for accommodating the needs of these health consumer experts
A008	https://drive.google.com/open?id=0BwQTUgazNAy5bjJLT09OSFNXRTA	American Association for Cancer Research	The Health Technology Assessment of Companion Diagnostics: Experience of NICE	Journal	2014	Companion diagnostics are used to aid clinical decision making to identify patients who are most likely to respond to treatment. They are becoming increasingly important as more new pharmaceuticals receive licensed indications that require the use of a companion diagnostic to identify the appropriate patient subgroup for treatment. These pharmaceuticals have proven benefit in the treatment of some cancers and other diseases, and also have potential to precisely tailor treatments to the individual in the future. However, the	This article could provide some insights into broader considerations, however i think it is largely OUT OF SCOPE.

						increasing use of companion diagnostics could place a substantial burden on health system resources to provide potentially high volumes of testing. This situation, in part, has led policy makers and Health Technology Assessment (HTA) bodies to review the policies and methods used to make reimbursement decisions for pharmaceuticals requiring companion diagnostics. The assessment of a pharmaceutical alongside the companion diagnostic used in the clinical trials may be relatively straightforward, although there are a number of challenges associated with assessing pharmaceuticals where a range of	

						alternative companion diagnostics are available for use in routine clinical practice	
A009	https://drive.google.com/open?id=0BwQTUgazNAy5RWxaY0lrSzcxYnc	BMC Medical Ethics	Technology assessment and resource allocation for predictive genetic testing: A study of the perspectives of Canadian genetic health care providers	Journal	2009	With a growing number of genetic tests becoming available to the health and consumer markets, genetic health care providers in Canada are faced with the challenge of developing robust decision rules or guidelines to allocate a finite number of public resources. The objective of this study was to gain Canadian genetic health providers' perspectives on factors and criteria that influence and shape resource allocation decisions for publically funded predictive genetic testing in Canada	Findings suggest that largely local and relatively ad hoc decision making processes are being made in relation to resource allocations for predictive genetic tests and that a more coordinated and, potentially, national approach to allocation decisions in this context may be appropriate
A010	https://dri	BMC Health Service Research	Study Protocol:Intro	Study Protocol	2009	Is only a study protocol- would be	

	ve.google.com/open?id=0BwQTUgazNAy5c0R6a3l1Y19acmc		ducing patient perspective in health technology assessment at the local level			good to see if the study has taken place. This study provides an opportunity to bridge the gap between HTA producers and its ultimate end-user: the patient. It will provide guidance to support local HTA units in Quebec and elsewhere in their decisions regarding patient participation. The framework developed could be applied to design and implement strategies for involving patients in HTA activities.	
A011	https://drive.google.com/open?id=0BwQTUgazNAy5cnZWV2	BMJ Publishing Group	European Medicines Agency is attacked over proposal to allow technology assessment bodies to sell advice to drug industry	News	2014	The European Medicines Agency has been criticised over its plan to allow health technology assessment bodies to provide confidential advice to drug companies in exchange for fees. A coalition of medicine advocates denounced	Again a broader consideration that you may or may not tie into your work.

	xlV2h4WHM					the practice, which they said was a clear conflict of interest.	
A012	https://drive.google.com/open?id=0BwQTUgazNAy5LUMxM09pVXRiQkU	International Journal of Technology Assessment in Health Care	Survey on the involvement of consumers in health technology assessment programs	Research Report/ Journal	2006	The aim of this study was to obtain information from members of the International Network of Agencies for Health Technology Assessment (INAHTA) on their involvement of consumers (patients, carers, and related organizations) in their programs	Of the thirty-seven agencies that provided responses, 57 percent involve consumers in some aspects of their HTA programs and 83 percent intend to involve consumers in the future. Summaries of HTA reports that are intended to be easily understood by consumers are prepared by 49 percent of the agencies, and 36 percent involve consumers in dissemination of HTA material.
A013	https://drive.google.com/open?id=0BwQTUgazNAy5NG1Vd2tFUkZIYkk	BMC Public Health	Medical device assessment: scientific evidence examined by the French national agency for health – a descriptive study	Journal	2012	This study aimed to ascertain level of evidence available for implantable medical devices (IMDs) access to reimbursement in France.	This study confirmed that level of evidence of clinical evaluation of implantable medical devices (IMDs) is low and needs to be improved

A014	https://drive.google.com/open?id=0BwQTUgazNAy5enJkSllGN2ZrRVU	BMC Health Service Research	Involving patients in HTA activities at local level: a study protocol based on the collaboration between researchers and knowledge users	Study Protocol	2012	Study objectives are to: 1) validate a reference framework for exploring the relevance and applicability of various models of patient involvement in HTA, 2) implement strategies that involve patients (including close relatives and representatives) at different stages of the HTA process, 3) evaluate intervention processes, and 4) explore the impact of these interventions on a) the applicability and acceptability of recommendations arising from the assessment, b) patient satisfaction, and c) the sustainability of this approach in HTA.	This project represents a unique opportunity for policy makers and researchers to work toward a common goal to test different forms of patient involvement in HTA and to evaluate them in order to produce useful knowledge regarding the implementation of patient involvement strategies in HTA and their possible effects and impacts.
A015	https://drive.google.com/open	BMC Health Service Research	Involving patient in the early stages of health technology assessment	Study Protocol	2014	The project objectives are: 1) setting up interventions to promote patient participation in three stages of the HTA	Assessing the impact of patient participation on the relevance of the topics suggested, the prioritization process, and the assessment plan from the point of view of patients and other groups involved in HTA.

	?id=0BwQTUgazNAy5b3huQ2JWS1pwTm8		(HTA): a study protocol			process: identification of HTA topics, prioritization, and development of the assessment plan of the topic prioritized; and 2) assessing the impact of patient participation on the relevance of the topics suggested, the prioritization process, and the assessment plan from the point of view of patients and other groups involved in HTA.	
A016	https://drive.google.com/open?id=0BwQTUgazNAy5VXhDTUtQZE8zcWM	Social Sciences & Medicine	"It all depends": Conceptualizing public involvement in the context of health technology assessment agencies	Journal	2010	The concept of public involvement is poorly articulated and little attention has been paid to the context of HTA agencies. This article investigates how public involvement is conceptualized in the HTA agency environment. Using qualitative concept analysis methods, we reviewed the HTA literature and the	Our analysis reveals that HTA agencies' role as bridges or boundary organizations situated at the frontier of research and policymaking causes the agencies to struggle with the idea of public involvement. The HTA community is concerned with conceptualizing public involvement in such a way as to meet scientific and methodological standards without neglecting its responsibilities to healthcare policymakers.

						websites of HTA agencies and conducted semi-structured interviews with informants in Canada, Denmark, and the United Kingdom.	
A017	https://drive.google.com/open?id=0BwQTUgazNAy5c1RVLVVERjZnbGs	International Journal of Technology Assessment in Health Care	Consumer involvement in the health technology assessment program	Journal	2004	This study aims to describe a cycle of development leading to sustainable methods for involving consumers in the management of a program commissioning health technology assessment	Over 4 years, procedures and resources have been developed to support six consumers attending seven to eight prioritization meetings a year; thirty to forty-five consumers each year commenting on research need for particular topics; thirty consumers a year commenting on research proposals, and twenty a year commenting on research reports. The procedures include clear job descriptions, induction and development days, clear briefing materials, payment for substantial tasks, and regularly seeking feedback to improve procedures
A018	https://drive.google.com/open?id=0BwQTUgazNAy5Rkx	Social Sciences & Medicine	Eliciting ethical and social values in health technology assessment: A participatory approach	Journal	2011	Our primary objective was to elicit a set of ethical and social values from citizens that could be used to guide Ontario's HTA evidentiary review and appraisal process. A secondary objective was to explore the feasibility of using	Over the course of five meetings, panel members progressed toward the identification of a set of core values e universal access, choice and quality care. These values were consistently prioritized as the core values that should be considered in the evaluation of health technologies and ensuing recommendations. Sustained and deliberative methods, like a citizens' panel, offer a promising approach for eliciting ethical and social values into HTA.

	wVXVZRlRKSUE					participatory approaches to elicit these values.	
A019	https://drive.google.com/open?id=0BwQTUgazNAy5ZUU2bm1zeTgyLXM	Value in Health	Health Technology Assessment in Canada: 20 Years Strong?	Journal	2009	Discussion surrounding the case of HTA's in Canada over the past 20 years. Highlighting shortcomings, challenges and considerations about the future.	It is difficult, if not impossible, for a single HTA body to meet the information needs of decision-makers unless it is operating within a single payer system, such as the United Kingdom. In Canada, HTA has evolved to include a combination of national and local initiatives, reflecting the decentralized nature of its health-care system
A020	https://drive.google.com/open?id=0BwQTUgazNAy5dkkxTTBlc2xGM3	Medical Decision Making	An Equity Framework for Health Technology Assessments	Journal	2012	This article develops a framework to help decision makers supplement the standard efficiency criteria of HTA and avoid building inequities, explicit or implicit, into their methods. The framework is intended as a first step toward creating a checklist for alerting decision	Two domains of equity are especially relevant in HTA. One is fairness of the procedures used in the conduct of HTAs. The other is equity as a decision criterion, like efficiency, for ranking health care interventions. We propose a practical and adaptable initial framework as the basis for the development of a more comprehensive typology (Note 4). It is practical because it is intended as a sequence of red flags to alert decision makers—and the designers of the systems within which they work—to matters of equity that might warrant integration into, or at least parallel consideration with, the usual efficiency analysis of HTAs. It is adaptable because the framework as it

	M					makers to a wide range of equity considerations for HTA. This framework is intended be used as part of the process through which advisory bodies receive their terms of reference; scope the agenda prior to the selection of a candidate intervention and its comparators for HTA; prepare background briefing for decision makers; and help to structure the discussion and composition of professional and lay advisory groups during the assessment process	currently stands is intended only as an initial step and what may be added is currently unknowable (at least, by us).
A021	https://drive.google.com/open?id=0BwQTUga	Social Sciences & Medicine	Dealing with moral dilemma raised by adaptive preferences in health technology assessment:	Journal	2013	The main contribution of this article is to show that a dialogue between ethics and economics, prior to an assessment, makes it possible to redefine the choice of effectiveness criteria	• The congenital nature of the two disabilities and the irreversible consequences of both GH treatment and cochlear implants leads to envisaging the existence of a moral dilemma arising from possible conflicts of preferences: the choice of proxy respondents who must estimate the value of health benefits provided by the two technologies could indeed have a determining impact on the results of the assessment, and hence on the funding of treatment by health

	zNAy5TnEteWRvUXhYeW8		The example of growth hormones and bilateral cochlear implants			(subjective well-being, capabilities or social outcomes), the choice of perspective (patients or the able-bodied), as well as the scope of assessment (medical and non-medical care).	insurance. • The main contribution of this article is to show that the dilemma could be resolved via a dialogue between ethics and economics, whose importance Sen stressed in his essay "On Ethics and Economics". • This dialogue indeed makes it possible to redefine the choice of perspective (patients or the able-bodied), as well as the perimeter of assessment (medical and non-medical care).
A022	https://drive.google.com/open?id=0BwQTUgazNAy5WEZNN2IvejlOQkU	Patient	A Pilot Study to Identify Areas for Further Improvements in Patient and Public Involvement in Health Technology Assessments for Medicines	Journal	2012	Patient and public participation in health technology assessment (HTA) of medicines has been cited as an important component of the decision making structure; however, how to actually achieve meaningful involvement is less understood	• The HTA process is becoming increasingly transparent to patients and the public; however, more effort is required to fully engage patients in the decision-making processes for medicine HTAs. • This pilot study identified three key areas for further advancement in this field, and recognized a need for further research in the areas of measuring the impact of patient engagement on decision making in medicine HTAs, as well as the best methods to better prepare patient advocacy groups through HTA education and training.
A023	https://drive.google.com/open?id=0	The Lancet	Offline: The error of our health technology assessment way	Journal	2013	This articles delves into some of the limitations of HTA's in the UK and elsewhere.	• There are two conclusions one might draw from the past 20 years of HTA in the UK and elsewhere. • First, an effective device, drug, or medical or surgical procedure has not been fully evaluated until its availability, accessibility, acceptability, and the quality of its delivery has been measured among all

	BwQTUgazNAy5dTIMWmd1ZUk5QUE						segments of the population. • Clinical effectiveness is only half the story of HTA. The other half is equity. And on equity-focused health technology assessment, the UK performs poorly. • Second, health systems have been incorrectly excluded from definitions of health technology. Health systems are health technologies. Until HTA programmes take health systems research more seriously, as many low and middle income countries are now doing, they will continue to miss important opportunities for strengthening and sustaining the health of their populations
A024	https://drive.google.com/open?id=0BwQTUgazNAy5YWRiZ2JMNDZBRTA	International Journal of Technology Assessment in Health Care	Socio-ethical issues in personalized medicine: a systematic review of English language health technology assessments of gene expression profiling tests for breast cancer prognosis	Journal	2015	The aim of this study was to catalogue ELSI content in HTAs of GEP tests for breast cancer prognosis and examine how this material is integrated in HTAs. (GEP= Gene Expression profile tests) ELSI= Ethical, legal, social issues	Despite a wide variety of important ELSI raised, these were rarely explicitly addressed in HTAs. Explicit treatment would increase their accessibility to decision-makers, and may augment HTA efficiency maximizing their utility. This is particularly important where complex Personalized Medicine applications are rapidly expanding choices for patients, clinicians and healthcare systems.
A025	https://dri	International Journal of	Health technology	Journal	2008	The goal of this study is to understand how	We contend that the use and dissemination of HTA reports by specific groups could help in widening the

	ve.google.com/open?id=0BwQTUgazNAy5ZklvWjFKdlpNdWM	Technology Assessment in Health Care	assessment use and dissemination by patient and consumer groups: Why and how?			and why patient and consumer organizations use HTA findings within their organizations, and what factors influence how and when they communicate their findings to members or other organizations.	debate around controversial health technologies. The implications and opportunities for HTA agencies relate to the following: (i) identification of "lay" organizations that could help in disseminating results; (ii) acknowledgement of a "lay" audience for HTA findings; (iii) strategic inclusion of advocacy groups during the assessment process for highly controversial technologies; and (iv) contribution of these organizations to the push efforts of knowledge transfer. Although HTA findings are often used by the patient and consumer organizations, key differences were observed in exactly how the four HTA reports were used. Three types of use (instrumental, conceptual, and symbolic) are reported and illustrated. We highlight the importance of the organization's mission and knowledge base in explaining the types of use observed.
A026	https://drive.google.com/open?id=0BwQTUgazNAy5Mzlwa21tSFhUd	Journal of Public Health	A rapid needs assessment of the provision of Health Technology Assessment in the south-west peninsula	Journal	2007	This rapid needs assessment evaluates the provision of HTA in the south-west peninsula, and its scope, content and quality. Semi-structured interviews and documentary analysis to assess the need for HTA were utilsed in these studies.	The quality of literature review in HTAs was variable and virtually none considered value for money. Informants felt there was insufficient provision of local HTAs. Local focus and clinical engagement were seen as key to the implementation of appraisal decisions, but this was threatened by weak links with commissioning and processes to prioritize decisions across primary care trusts. Local provision of HTAs in the peninsula is at full stretch and quality is variable. Lack of consideration of value for money and variation in quality in HTAs present a potential risk in terms of clinical and corporate governance and may leave appraisal

	m8						decisions open to challenge. Links between committees using HTA and with commissioning are weak, limiting capacity and undermining financial and health benefits. Furthermore, incongruent prioritization processes may be leading to unequal access to technologies.
A027	https://drive.google.com/open?id=0BwQTUgazNAy5Q3h0UlN3S3FNczg	International Journal of Technology Assessment in Health Care	Patient-based health technology assessment: A vision of the future	Journal	2007	The aim of this study was to develop a working definition of patient-based HTA, to identify the current barriers to adopting a patient-based model, and to formulate a vision of how a patient-based HTA could be used to promote patient empowerment and patient-centered care.	Present-day HTA is broad and has numerous stakeholders, with none so important as the patient. By asking patient-oriented questions in HTA and better involving patients throughout the entire process, we can easily promote patient empowerment, and as such make patients more capable to play a more active role in healthcare decision making. In the ideal setting, a patient-based HTA would promote patient knowledge by providing access to information and promoting an informed dialogue between patients and their healthcare professionals. To implement a patient-based HTA, the focus must turn to the patient's issues and incorporate each patient's unique perspective and preferences. Processes must change to increase patient participation in all levels of HTA and aim to promote empowered patients who can make informed decisions
A028	https://drive.google.com/open?id=0	International Journal of Technology Assessment in Health Care	Does the public think it is reasonable to wait for more evidence before	Journal	2010	The project's other objective is to examine the lay public's views on a case in which patients' publicly funded access to an innovative health	The majority of council members agreed that the approach taken by the government was reasonable and in the best interests of its citizens. The council did express concerns regarding certain aspects of the case, including about the length of time it is taking to obtain further evidence

	BwQTUgazNAy5RnIxQlJ6UFFIMW8		funding innovative health technologies? The case of PET scanning in Ontario			technology is being delayed until there is sufficient evidence to justify a coverage decision. The case considered is the Ontario (Canada) government's decision to restrict access to positron emission tomography (PET) scans until further evidence becomes available. The case was deliberated on by twenty-six members of the Toronto Health Policy Citizens' Council, with a follow-up survey administered to individual council members	Public support for arrangements that limit access to new technologies will likely vary depending on the details of the specific arrangement being proposed. Deliberative public dialogue can be effectively used to identify cases the general public is most likely to support
A029	https://drive.google.com/open?id=0BwQ	BMJ Publishing Group	Public involvement in research should be "second nature" by 2025, review concludes	Journal	2015	The Breaking Boundaries review was commissioned by the director general of research and development and chief medical officer in March 2014 to assess	The report outlined six strategic goals that the institute should work towards for 2025. These include ensuring that opportunities to engage with research are made visible to the public and seized; that public involvement is locally driven but strategically consistent; that the public's contribution is valued and required as part of high quality research; and that evidence of what works is collected and

	TUgazNAy5bjZleHJkS2xiUkE					how successful the institute has been in achieving public involvement and to make recommendations to build on the achievements so far.	disseminated. The report also gave 11 specific recommendations for achieving this vision, central to which is that the institute should commission the development of a set of values, principles, and standards for public involvement. All NIHR leaders, funded researchers, and staff should also receive an induction in public involvement, it added
A030	https://drive.google.com/open?id=0BwQTUgazNAy5eDZCdUZidC04OWs	MJA	Health technology assessment in Canada: diversity and evolution	Journal	2007	• Canada has health technology assessment programs at national, provincial and local levels. The context of HTA's in Canada is explored and 'lessons for Australia' are also mentioned.	The programs have been complementary in providing advice to decision makers in health care. A national strategy for the management of health technologies is expected to strengthen communication with policy areas.
A031	https://drive.google.com/open?id=0BwQTUgazNAy	Australian Government	Review of Health Technology Assessment in Australia	Government publication	2009	A key objective of the HTA Review is to address the regulatory burden on business that results from HTA processes, to ensure that those processes are efficient, measured and proportionate. The	The HTA Review recommends that Commonwealth HTA processes should: • all follow a set of shared objectives and principles; • be part of an open, transparent, integrated system; • make information easily available from a central website, including more information on how technologies will be assessed and how decisions are made; • provide improved opportunities for sponsor and

	5OE5Zd1B2VEdRZ28					HTA Review is to identify opportunities for reform of the processes that may be poorly designed, duplicated or unnecessary, imposing unwarranted costs and complexity on business and discouraging innovation.	stakeholder input, including expanded options for seeking review of decisions; • operate through a single entry point to assist stakeholders by receiving, guiding and monitoring all applications for reimbursement; • be more flexible in dealing with novel and complex technologies by coordinating assessments and allowing different aspects of complex technologies to be assessed at the same time; • speed up Medical Services Advisory Committee assessments by allowing sponsors to supply their own assessments and have these critiqued; • simplify administration of the Prostheses List by streamlining administrative processes and removing duplication; and • reform post-market surveillance of health technologies to strengthen patient safety and value for money for taxpayers.
A32	https://drive.google.com/open?id=0BwQTUgazNAy5djR3cDkwbEdxc2M	Consumers Health Forum of Australia	Review of the Health Technology Assessment (HTA) Information Paper	Review paper	2009	CHFA touch on various facets of HTA. There is considerable reference to the role of the consumer in HTA's interwoven throughout the paper.	Consumers are concerned that the current assessment processes do not recognise that the interaction of what are effectively two or more different technologies may have different health outcomes to when they are used alone. Consumers are also concerned that the current HTA arrangements delay the introduction of new technologies for what may be years at a time. While CHF does not support untested technologies being introduced to the Australian market, the current time taken for assessment for some products appears unnecessarily long. For those consumers in particular who are managing a terminal condition, this

							is unacceptable. With respect to the cost-effectiveness of HTA, some consumers are not convinced that the plethora of 'substantially equivalent' technologies currently listed and subsidised by the Australian Government is justified. Consumer observations and experiences of health technology need to be included in post-marketing surveillance of medical devices and medicines in a systematic way. Consumers are very concerned that their accounts of adverse events are not regarded as credible within the health industry. This is a serious public health issue, as it is consumers who are using health technology who are most likely to observe and report any ill effects. CHF consultations indicate that key issues for consumers with respect to co-dependent and hybrid technologies include (i) being able to provide expertise in evaluating these technologies; (ii) having the infrastructure and processes that can handle the information sources and data management from various evidence sources; and (iii) having strong national and international collaborative networks so that expertise can be drawn from all over the world
A033	https://drive.google.com/open	Consumer Health Forum of Australia	Consumer Participation in the Review of Health Technology Assessment	Report	2009	The report is written from a consumer perspective, and specifically outlines consumer opinions, concerns and	Recommendation 1: Robust mechanisms should be developed to take into account consumer experiences and needs in all HTA stages through mechanisms such as: o Consumer representatives on committees; o Use of consumer impact statements; o Public reporting of consumer

	?id=0BwQTUgazNAy5SXUyMUsydFN4VE0		Report on outcomes of consumer consultations			suggestions raised with CHF in its consultations.	experiences with devices and technologies; and o International models as appropriate (eg Citizens‟ Councils, Interest SubGroups) Recommendation 2: Rigorous post market surveillance mechanisms should be established, ideally governed by a separate body, to the body conducting assessments, to enable the capture, analysis and reporting of information on adverse events and for this information to feed back into assessment processes. Recommendation 3: The HTA system should have the capacity to reduce red tape, bureaucracy and inefficiencies in the system, including through a single entry point into the system and a process for interim approval for some devices, to ensure that they are available to consumers more quickly, pending full assessment. Recommendation 4: HTA pre-market assessment processes must apply clear risk criteria in the assessment of evidence for applications with consumer safety allocated the highest priority. Recommendation 5: There should be mechanisms for regularly reviewing the technologies on the ARTG, and removing them from the ARTG when they have been shown to be dangerous, when they are superseded by superior products, or when they are no longer being used. Recommendation 6: Consumer education programs should be developed to ensure that consumers have a strong understanding of both medical devices and technologies and the HTA system designed to regulate their use in Australia. Recommendation 7: A single rigorous code of

							conduct for all pharmaceutical and therapeutic goods industries with appropriate sanctions for non-compliance with the code should be established.
A034	https://drive.google.com/open?id=0BwQTUgazNAy5TWF3amZwaVNVNWs	International Journal of Technology Assessment in Health Care	The history of health technology assessment in Australia	Journal	2009	HTA in Australia now has a long history and is well established as a source of advice to health decision makers. Challenges remain in extending the scope of assessments, developing more transparent approaches in some areas, and consistently applying appropriate standards.	Most HTA activity in Australia has been associated with provision of advice for the two national subsidy programs, Medicare, and the Pharmaceutical Benefits Scheme (PBS). National advisory bodies established by the federal government have had a prominent role. Assessments from the advisory bodies have had a major influence on decisions related to Medicare and the PBS, and in some other areas. Technologies without links to the national subsidy schemes, and those that are widely distributed, have been less well covered by HTA. To some extent these are addressed by evaluations supported by state governments, but details of approaches taken are not readily available
A035	https://drive.google.com/open?id=0BwQTUgazNAy5ZjNQaFEtNUtSVkU	MJA-Health Care	Health technology assessment in England: assessment and appraisal	Journal	2007	Discusses the state of HTA's in England. Also provides commentary on the Australian context, highlighting differences.	The Health Technology Assessment (HTA) Programme in England is a government-funded but independent research program. • It is “needs-led”, identifying technologies of most importance to the National Health Service and commissioning research to provide answers on these technologies useful to policymakers, clinicians and patients. • It is “science-added”, refining problems to researchable questions and working with researchers to ensure that the question is addressed, and disseminating the findings to key audiences.

							• There is a clear distinction in England between assessment (a scientific process and the role of the HTA Programme) and appraisal (the role of policymakers, like the National Institute for Health and Clinical Excellence).
A036	https://drive.google.com/open?id=0BwQTUgazNAy5b3BjNEQ4V2N2VHM	Journal of Health Politics, Policy and Law	Public Engagement in Health Technology Assessment and Coverage Decisions: A Study of Experiences in France, Germany, and the United Kingdom	Journal	2013	This article explores operational processes and underlying rationales of public engagement at HTA agencies in France, Germany, and the United Kingdom. The analysis is based on website information, legal framework documents, published and gray literature, and semi structured, in-depth interviews with top officials at these agencies	Engagement processes differ across agencies, particularly regarding the areas in which the public is involved, which groups of the public are involved, what weight they have in influencing decisions, how they are recruited and supported, and how potential conflicts of interests are addressed. Different emphases on rationales and drivers behind public engagement partly reflect the respective political environments. Interviewees indicated a range of benefits of engagement and factors influencing success or failure. The results highlight the need to be clear about the purpose and conduct of engagement in order to maximize the benefits of this increasingly widespread policy tool.
A037	https://drive.google.com/open?id=0BwQTUgazNAy	Expert Reviews Ltd	Role of patient and public participation in health technology assessment and coverage decisions	Journal	2011	In this article, we summarize findings from peer-reviewed and 'grey' literature, and discussions with key informants to determine potential roles for patients and the public in HTA and coverage decision-	A review of 'grey' literature, key informant interviews and a workshop of Canadian researchers, decision-makers and patient representatives with an interest in public and patient involvement in coverage decision-making identified several issues related to such approaches: • Open (public) committee meetings: public and patient representatives on committees have expressed discomfort in expressing their views in

	5UERockEwbl96VEE					making. We also summarize existing roles for both groups in jurisdictions	public, fearing that their views may not always align with the public, in its entirety; • Training of patient or public representatives on committees: to ensure that patient or public representatives feel able to contribute meaningfully to discussions, there is a need for educational opportunities that introduce them to basic terms, concepts and policy options; • Lack of resources available to patient organizations to assist them in completing submissions: many patient/carer organizations are not adequately resourced to make submissions, which can be complex and multidimensional. Consequently, only large, well-funded (often by industry) groups may be able to exercise this option
A038	https://drive.google.com/open?id=0BwQTUgazNAy5emxzTl90ME9Wd1k	International Journal of Technology Assessment in Health Care	Involvement of consumers in health technology assessment activities by INAHTA agencies	Journal	2013	The survey results suggest that there is a trend to increased involvement of consumers by the INAHTA agencies in their programs but that the level of involvement remains relatively limited. The manner of consumer participation varies between agencies.	Of the thirty-three agencies that provided responses, 67 percent involve consumers in some aspects of their health technology assessment (HTA) programs, compared with 57 percent in 2005. As in the earlier survey, most agencies reporting involvement have contact with consumer or patient organizations and a large minority also involve individual consumers. Summaries of HTA reports that are intended to be easily understood by consumers are prepared by 84 percent of the agencies, and 42 percent involve consumers in dissemination of HTA material. In both areas, there was some increase from the levels previously reported
A039	http:/	Department of	Medicare	Government	20	How services can be	

	/web.archive.org/web/20151511123 3210/http://www.health.gov.au/internet/main/publishing.nsf/Content/MBSReview Taskforce	Health	Benefits Schedule Review Taskforce	report	15	aligned with contemporary clinical evidence and improve health outcomes for patients.	
A040	http://www.health.gov.au/interne	Department of Health	HTA Policy framwork	Government report	2011	An overview of the current Australian Government HTA processes used to inform decisions about the registration of health technologies	The Australian Government accepted two recommendations in the review, one point which included that the policy framework includes a vision, goal, objectives and principles which provide a systematic and consistent approach to HTA, and an explicit, high-level statement of direction for the implementation and integration of the current HTA

	t/hta/publishing.nsf/Content/policy-1					for use in Australia,	functions to form a coherent system.
A041	https://www.adelaide.edu.au/ahta/pubs/AHTA_factsheet_updated_July_2015.pdf	University of Adelaide	Adelaide Health Technology Assessment (AHTA)		2011	In a systematic manner AHTA identifies, collates, appraises, and synthesises evidence on different medical services to inform policy makers and health professionals on whether an intervention is effective and safe. Economic modelling is conducted to allow an assessment of the cost-effectiveness of these medical services.	
A042	http://www.efpia.eu/uploads/Mo	Chalres River Associates for EFPIA	A comparative analysis of the role and impact of Health Technology	Research Report		A comparative assessment of the role and impact of Health Technology Assessment (HTA) in different parts of the world, for example	nbj

	dules/Documents/hta-comparison-report-updated-july-26-2011-stc.pdf		Assessment			how different systems use HTA, the basis of the approach they apply, how it works in practice and the consequences for the key stakeholders.	
A043	http://stm.sciencemag.org/content/scitransmed/7/313/313ed12.full.pdf	Science Translational Medicine	Hearing Voices: FDA seeks advice from patients	Editorial	2015	New patient engagement advisory committee set up by FDA CDRH to advise FDA on issues relating to the regulation of medical devices and their use by patients.	Advisory Model- patients work hand in hand with regulators and stakeholders. Engage patients at the same time as the emergence of medical device innovation, integration of digital health technologies, new models for clinical trials, and patient engagement

A044	http://www.sciencedirect.com.ez.library.latrobe.edu.au/science/article/pii/S0168851012002813	Health Policy	Diffusion and use of health technology assessment in policy making: What lessons for decentralised healthcare systems?	Journal Article		There is probably need to rethink the multi-layer organizational framework of HTA in Italy by leveraging on current knowledge and efficient redistribution of activities across regions. We would advise for different jurisdictions playing different roles while achieving similar health outcomes for their patients, rather than jurisdictions aiming at doing exactly the same things resulting in unequal access to healthcare service provision.	
A045	http://www.ncbi.nlm.nih.gov/books/NBK56846/pd	Health Technology Assessment	Avoiding and identifying errors in health technology assessment models: qualitative study and methodological review	Journal Article	2010	This study seeks to understand the nature of errors within HTA models, to describe current processes for minimising the occurrence of such errors and to develop a first classification of errors to aid discussion of potential	Published definitions of overall model validity comprising conceptual model validation, verification of the computer model, and operational validity of the use of the model in addressing the real-world problem are consistent with the views expressed by the HTA community and are therefore recommended as the basis for further discussions of model credibility. Discussions of model credibility should focus on risks, including errors of implementation, errors in matters of judgement and violations. Discussions of modelling risks should reflect the potentially complex

	f/Bookshelf_NBK56846.pdf					strategies for avoiding and identifying errors.	network of cognitive breakdowns that lead to errors in models and subsequent failures in decision support. Existing research concerning the cognitive basis of human error should be brought into the examination of modelling errors. There is a need to develop a better understanding of the skills requirements for the development, operation and use of HTA models. The qualitative interviews highlighted a number of barriers to model checking. However, it was indicated that increasing time and resources would not necessarily improve model checking activities without a matched increase in their prioritisation. The authors take the view, as supported within the methods literature, that it is the interaction between the modeller and client in developing mutual understanding of a model that establishes a model's significance and its warranty. This position highlights that model credibility is the central concern to decision makers in using models. It is crucial then that the concept of model validation should not be externalised from the decision-makers and the decision-making process.
A048	http://web.archive.org/web/20151117045807/http://ww	BMC Medicine	Six 'biases' against patients and carers in evidence-based medicine	Journal Article	2015	Evidence-based medicine (EBM) is maturing from its early focus on epidemiology to embrace a wider range of disciplines and methodologies. At the heart of EBM is the patient, whose informed choices have long been recognised	The six 'biases' against patients and carers in evidence-based medicine are: •limited patient input to research design, •low status given to experience in the hierarchy of evidence, •a tendency to conflate patient-centred consulting with use of decision tools; •insufficient attention to power imbalances that suppress the patient's voice, •over-emphasis on the clinical consultation,

	w.biomedcentral.com/content/pdf/s12916-015-0437-x.pdf					as paramount. However, good evidence-based care is more than choices. We discuss six potential 'biases' in EBM that may inadvertently devalue the patient and carer agenda To reduce these 'biases', EBM should embrace patient involvement in research, make more systematic use of individual ('personally significant') evidence, take a more interdisciplinary and humanistic view of consultations, address unequal power dynamics in healthcare encounters, support patient communities, and address the inverse care law.	•a focus on people who seek and obtain care (rather than the hidden denominator of those that do not seek or cannot access care).
A049	http://web.archive.org/we	Medical Journal of Australia	Over 150 potentially low-value health care practices: an	Journal Article	2012	To develop and apply a novel method for scanning a range of sources to identify existing health care	The list of health care services produced provides a launchpad for expert clinical detailing. Exploring the dimensions of how, and under what circumstances, the appropriateness of certain services has fallen into question, will allow prioritisation within health

	b/20151117065907/https://www.mja.com.au/system/files/issues/197_10_191112/els11083_fm.pdf		Australian study			services (excluding pharmaceuticals) that have questionable benefit, and produce a list of services that warrant further investigation.	technology reassessment initiatives
A050	http://web.archive.org/web/20151117102634/http://fiel	The Lancet	Drug development for neglected diseases: a deficient market and a public-health policy failure	Journal Article	2002	There is a lack of effective, safe, and affordable pharmaceuticals to control infectious diseases that cause high mortality and morbidity.	The pharmaceutical industry argues that research and development is too costly and risky to invest in low-return neglected diseases, and public and private initiatives have tried to overcome this market limitation through incentive packages and public-private partnerships. The lack of drug research and development for "non-profitable" infectious diseases will require new strategies Private-sector research obligations should be explored, and a public-sector not-for-profit research

	dresearch.msf.org/msf/bitstream/10144/28441/1/Access%20Trouiller%202020 02.pdf						and development capacity promoted.
A051	http://web.archive.org/web/20151118033233/http://www.en.ipea.gov.br/p						

	articipacao/images/pdfs/participacao/2000%20public%20participation%20methods.pdf						

Additional information

An interview with NICE

The following passage is an edited version of an interview, conducted with a NICE employee about public involvement in the work of NICE. It has been shared with their permission, but anonymised.

Significant sentences are in **bold.**

What do you feel has been the most effective way of involving the public? What has been most challenging?

The most effective way has been **involving patients, people who use services, carers and other members of the public as equal partners** in the development of our NICE guidance. This means that they are appointed to NICE's independent committees alongside professional members to help NICE to develop our guidance – they have equal status to professional committee members and play a full role in interrogating the evidence so that they can use their unique viewpoint to inform the deliberations of the committee that result in NICE's recommendations.

I would say that this has also been the most challenging strand of our public involvement methods – the principle of equal status for lay members on a NICE committee is something that we really need to keep a close eye on – chatting regularly to the lay members to make sure that they feel confident and able to contribute, as well as feeling that their contributions are valued by NICE and the professional committee members. **The difference that a good chair makes to a lay member's confidence and contributions is often quite startling** – so it's important for us to develop good relationships with the teams at NICE who work with their committee, and their chairs so that we can address any issues as and when they arise.

We would also dearly love to have more lay members on each NICE committee, as this also plays a big part in increasing confidence and contributions from a lay perspective, but unfortunately we usually have 2 – 3 lay members on a committee of 15 people, which means that lay members are often quite heavily outnumbered by professional members.

How do you support the public (patients, carers etc) to get involved? (e.g. Do you have any specific training, financial support or is it more one on one support provided by your colleagues?)

Yes to all three! **We aim to provide training for lay members wherever possible**, and the content of these varies depending on the NICE work programme that the lay member has been appointed to work with. As an example, with NICE guidelines covering clinical and social care, our training workshop for new lay members covers the principles and methodology of guideline development, the basics of health economics, a previous example of how recommendations have been developed, as well as the opportunity to hear from lay members

who have already been through this process and can therefore share really helpful hints and tips with the new lay members.

In terms of financial support, we offer an attendance fee to lay members (£150 for a full day meeting, or £75 for a half day meeting), as well as covering travel and accommodation, carer and subsistence expenses. The attendance fee is only offered to lay members on a NICE committee – in recognition of the fact that their contribution is valuable and because professional members very often work with NICE as part of their day job and professional development.

The Public Involvement Programme at NICE (PIP – which is the team that I work for) supports lay members, as well as the organisations who advocate for their interests, to get involved in the development of NICE guidance. Part of this means that someone in the PIP is assigned to be the public involvement lead for each and every lay member who works with NICE. This means that we speak with them at key points in the guidance development process, as well as always being available for them to get in touch with to discuss any concerns that they think we may be able to help with.

It's basically about relating the principles of guidance development in a way that makes sense to someone who doesn't usually work with evidence as part of their everyday life. As part of this support, we also usually have something called a 'Welcome Pack' which we send to newly appointed lay members – it covers tips for success, a glossary of terms that they are likely to come across in evidence reviews, a list of useful websites that they can use to undertake further research before each meeting, as well as an FAQ document about committee meetings (covering things about what to expect in a committee meeting and a how to guide).

How do you think public involvement in the whole process could be improved? Is there anywhere the public shouldn't or can't be involved?

No public involvement methodology is ever perfect. It's about constantly reflecting on the experiences and outcomes of involvement for members of the public, and using that feedback to adjust our processes so that they meet the needs of lay members and their organisations as best they can. I've already talked about this above, but improvement for me lies in proper training for NICE committee chairs, making sure that our support processes are carefully tailored to the individual lay member depending on their own unique needs, ensuring that NICE committees have a respect and appreciation for the contribution of their lay member colleagues, and making sure that the NICE centres responsible for selecting lay members to join their committees truly know and understand what makes a good lay member so that we are working with people who are truly passionate about what they are doing and are able to make a significant contribution to the work of the committee.

I don't believe that there is any part of NICE's processes where patients, people who use services, carers and other members of the public should not be involved. However, in an organisation that is locked in by tight time constraints, true and authentic co-production still seems some distance away. For example, I think that it would be incredibly worthwhile to involve lay members in all of NICE's scoping phases – which would mean that they are involved in determining what the guidance will and, importantly, won't cover. For clinical and public health guidelines, this phase usually happens before committee members are appointed for a particular topic. We therefore currently rely on organisations who advocate for the interests of the public to take part in consultations on the draft scope – which is effective to an extent, although I anticipate will become more problematic as voluntary and community sector organisations move towards an ever tightening squeeze on their resources, which is clearly going to impact on their ability to take part in the NICE guidance development process.

For the moment then, it's about working with NICE's lay members to demonstrate exactly what it is that the lay perspective adds to guidance development and just how effective it can be when it's done well. In this way, we will be able to shape and refine NICE's processes and methodologies as we move forward for the benefit of the people most affected by our guidance.

There are also particular difficulties with involving vulnerable groups in NICE's work – for example, we don't seem to do particularly well in attracting lay member applications from children and young people, and expecting people with profound learning difficulties to take part in NICE committees would be a stretch too far for them. However there are ways around these kinds of things – in a situation where it had not been possible to recruit a lay member with personal experience of the issue or condition under consideration, we would advise the NICE teams to undertake some focused group work with these people to get their insight either in to our ideas for draft recommendations and what they would mean for them, or to ask for their opinions on what matters most to them in a particular treatment or care pathway where there is a lack of published evidence available for the committee to glean this information from.

If you were setting up public involvement in the HTA process, what would you do?

Other than NICE, I believe that CADTH in Canada and the SMC in Scotland do public involvement in the HTA process well. If I were to have the indulgence of setting up my own HTA process, I'd come up with a hybrid of the three as a starting point.

- My preferred pointers for a possible hybrid of the three would be:
- All three have a dedicated patient support team.
- Patient participation in scoping (NICE)
- Guide and one on one help with patient group submissions – (SMC)
- Lay members presenting the patient evidence at committee happens at all three, although SMC and CADTH highlight this more than NICE – they both have specific time or a slot set aside for the patient views and preferences.
- 'Patient & Clinician Engagement' meetings for ultra-orphan and end-of-life treatments (SMC)
- Patient experts at the committee meeting – and one on one support for them – (NICE)
- Consultation (NICE)
- Right to Appeal (NICE)

- Feedback letter to patient groups about their submissions – this is really good (CADTH)

Health Technology Assessment international

Health Technology Assessment international have an online 'Citizen and Patient Involvement library (CPIL)'[119]. It is a useful collection of literature, divided into subject headings such as 'Citizen deliberations, Patient and public involvement' and 'Patient and public involvement', however, the section titled 'Framework, models, roles' returns no results.

[119] http://web.archive.org/web/20151124001716/http://vortal.htai.org/?q=cpil

Accessing documents

This document and all those associated with this report can be accessed using the following link:

https://goo.gl/QRPVpS

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